



PMI RESEARCH & DEVELOPMENT

Study ZRHM-REXA-08-US Clinical Study Report Appendix 15.2 Tables

Study Title:	A randomized, controlled, open-label, 3-arm parallel group, multi-center study to demonstrate reductions in exposure to selected smoke constituents in apparently healthy smokers switching to the Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol) or observing smoking abstinence, compared to continuing to use menthol conventional cigarettes, for 5 days in confinement and prolonged by 86 days in an ambulatory setting
Study Number:	ZRHM-REXA-08-US
Product Name:	Tobacco Heating System 2.2 Menthol (THS 2.2 Menthol)
Study Initiated (first subject screened):	17 December 2013
Study Completed (last subject last visit):	12 October 2014
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Version:	1.0
Date:	25 May 2016

This study was conducted in accordance with Good Clinical Practice.

Confidentiality Statement

This document is confidential. Disclosure of any of its contents to third parties is not permitted except by the prior written consent of Philip Morris Products S.A.



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15.2 SUMMARY TABLES



15.2.1 Disposition and Background Data Summary Tables

**Table 15.2.1.1 Summary of Subject Disposition - All Screened Subjects**

Status	Overall Screened (N=659) n(%)
Screen failures	495 (75.1)
Screening failures, without product test	494 (75.0)
Screening failures, with product test	1 (0.2)
Completed safety follow-up	0
Reason for screen failure	
Entry criteria not met	445 (67.5)
Withdrawal by subject	24 (3.6)
Adverse events	0
Other	26 (3.9)
Enrolled	164 (24.9)
Enrolled not randomized	4 (0.6)
Enrolled not randomized who completed safety follow-up	4 (0.6)
Randomized	160 (24.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Discontinued refers to randomized subjects who discontinued from the study before the planned discharge at Day 91; Completed at Period X Visit refers to randomized subjects who did not discontinue the study before the completion of study assessments at Period X Visit.

Note: Percentages for disposition prior to randomization are based on the number of subjects screened. Percentages for 'Completed safety follow-up' under 'Screening failures, with product test' are based on the number of subjects who screen failed with the product test. Percentages for disposition after randomization are based on the number of subjects randomized indicated in the column header (N), apart from the Overall column where only percentages of completed and discontinued refer to the total number of subjects randomized.

Note: Period 1 to Period 4 refers to the confinement, 30, 60, and 90 day periods, respectively.

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**Table 15.2.1.1 Summary of Subject Disposition - All Screened Subjects**

Status	THSm2.2 (N=80) n(%)	mCC (N=41) n(%)	SA (N=39) n(%)	Overall Randomized (N=160) n(%)
Completed Period 1	80 (100.0)	40 (97.6)	34 (87.2)	154 (96.3)
Completed Period 2	79 (98.8)	40 (97.6)	33 (84.6)	152 (95.0)
Completed Period 3	76 (95.0)	37 (90.2)	33 (84.6)	146 (91.3)
Completed Period 4	73 (91.3)	35 (85.4)	31 (79.5)	139 (86.9)
Completed safety follow-up	79 (98.8)	41 (100.0)	38 (97.4)	158 (98.8)
Discontinued	7 (8.8)	6 (14.6)	8 (20.5)	21 (13.1)
Discontinued Period 1	0	1 (2.4)	5 (12.8)	6 (3.8)
Discontinued Period 2	1 (1.3)	0	1 (2.6)	2 (1.3)
Discontinued Period 3	3 (3.8)	3 (7.3)	0	6 (3.8)
Discontinued Period 4	3 (3.8)	2 (4.9)	2 (5.1)	7 (4.4)
Discontinued safety follow-up	1 (1.3)	0	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Discontinued refers to randomized subjects who discontinued from the study before the planned discharge at Day 91; Completed at Period X Visit refers to randomized subjects who did not discontinue the study before the completion of study assessments at Period X Visit.

Note: Percentages for disposition prior to randomization are based on the number of subjects screened. Percentages for 'Completed safety follow-up' under 'Screening failures, with product test' are based on the number of subjects who screen failed with the product test. Percentages for disposition after randomization are based on the number of subjects randomized indicated in the column header (N), apart from the Overall column where only percentages of completed and discontinued refer to the total number of subjects randomized.

Note: Period 1 to Period 4 refers to the confinement, 30, 60, and 90 day periods, respectively.

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**Table 15.2.1.2 Summary of Reasons for Discontinuations - FAS**

Discontinuation	THSm2.2 (N=80) n (%)	mCC (N=41) n (%)	SA (N=39) n (%)	Overall FAS (N=160) n (%)
Total no. of discontinuations	7 (8.8)	6 (14.6)	8 (20.5)	21 (13.1)
Reason for discontinuation				
Adverse events	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Protocol violation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Withdrawal by subject	2 (2.5)	3 (7.3)	6 (15.4)	11 (6.9)
Lost to follow-up	3 (3.8)	2 (4.9)	0 (0.0)	5 (3.1)
Physician decision	1 (1.3)	0 (0.0)	1 (2.6)	2 (1.3)
Other	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.3.1 Summary of Protocol Deviations - Safety Population**

Classification of Deviation	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Total	80 (100.0)	1749	41 (100.0)	935	39 (100.0)	542	160 (100.0)	3226
Major	47 (58.8)	107	9 (22.0)	10	34 (87.2)	78	90 (56.3)	195
With evaluability impact	47 (58.8)	106	7 (17.1)	7	33 (84.6)	77	87 (54.4)	190
Mis-Randomization	4 (5.0)	4	4 (9.8)	4	5 (12.8)	5	13 (8.1)	13
Violation			1 (2.4)	1	1 (2.6)	1	2 (1.3)	2
Other	1 (1.3)	1	2 (4.9)	2			3 (1.9)	3
Mis-use of product in period 1					11 (28.2)	11	11 (6.9)	11
Mis-use of product in period 2	38 (47.5)	38			19 (48.7)	19	57 (35.6)	57
Mis-use of product in period 3	37 (46.3)	37			19 (48.7)	19	56 (35.0)	56
Mis-use of product in period 4	26 (32.5)	26			22 (56.4)	22	48 (30.0)	48
Without evaluability impact	1 (1.3)	1	3 (7.3)	3	1 (2.6)	1	5 (3.1)	5
Violation	1 (1.3)	1	2 (4.9)	2	1 (2.6)	1	4 (2.5)	4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Subjects are counted only once per deviation category but can be counted in more than one deviation category.

**Table 15.2.1.3.1 Summary of Protocol Deviations - Safety Population**

Classification of Deviation	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Other			1 (2.4)	1			1 (0.6)	1
Minor	79 (98.8)	1642	41 (100.0)	925	39 (100.0)	464	159 (99.4)	3031
Assessment missing	77 (96.3)	609	40 (97.6)	336	39 (100.0)	180	156 (97.5)	1125
Concomitant medication			1 (2.4)	1	1 (2.6)	2	2 (1.3)	3
Time deviation	67 (83.8)	491	36 (87.8)	292	28 (71.8)	117	131 (81.9)	900
Time missing	26 (32.5)	91	16 (39.0)	48	8 (20.5)	25	50 (31.3)	164
Violation	70 (87.5)	451	37 (90.2)	248	31 (79.5)	140	138 (86.3)	839

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Subjects are counted only once per deviation category but can be counted in more than one deviation category.

**Table 15.2.1.3.2 Analysis Sets and Reasons for Exclusions from Analyses**

Population Sets	THSm2.2 n (%)	mCC n (%)	SA n (%)	Product Test n (%)	Screen Failure n (%)	Overall n (%)
Subjects screened	80	41	39	5	494	659
Subjects included in Safety Population	80	41	39	5	0	165
Subjects excluded from Safety Population	0	0	0	0	494	494
Not exposed to THSm2.2	0	0	0	0	494	494
Total Subjects Randomized	80	41	39	NA	NA	160
Subjects included in Safety Population	80 (100)	41 (100)	39 (100)			160 (100)
Subjects excluded from Safety Population	0 (0.0)	0 (0.0)	0 (0.0)			0 (0.0)

Note: NA = Not applicable; mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages appearing after randomization are based on the number of randomized subjects in each column.

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

**Table 15.2.1.3.2 Analysis Sets and Reasons for Exclusions from Analyses**

Population Sets	THSm2.2 n (%)	mCC n (%)	SA n (%)	Product Test n (%)	Screen Failure n (%)	Overall n (%)
Subjects included in FAS	80 (100)	41 (100)	39 (100)			160 (100)
Subjects included in PP Set						
Period 1	75 (93.8)	35 (85.4)	24 (61.5)			134 (83.8)
Period 2	40 (50.0)	34 (82.9)	13 (33.3)			87 (54.4)
Period 3	39 (48.8)	35 (85.4)	12 (30.8)			86 (53.8)
Period 4	47 (58.8)	32 (78.0)	9 (23.1)			88 (55.0)

Note: NA = Not applicable; mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages appearing after randomization are based on the number of randomized subjects in each column.

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

**Table 15.2.1.3.2 Analysis Sets and Reasons for Exclusions from Analyses**

Population Sets	THSm2.2 n (%)	mCC n (%)	SA n (%)	Product Test n (%)	Screen Failure n (%)	Overall n (%)
Subjects excluded from PP Set for Period 1						
Has major protocol deviations not compliant	0 (0.0)	0 (0.0)	11 (28.2)			11 (6.9)
Access to medical records were granted for SDV and data entry after withdrawal of PHI authorization	1 (1.3)	0 (0.0)	0 (0.0)			1 (0.6)
Has other major protocol deviations impacting evaluability	4 (5.0)	6 (14.6)	6 (15.4)			16 (10.0)
Discontinued in previous period	0 (0.0)	0 (0.0)	0 (0.0)			0 (0.0)

Note: NA = Not applicable; mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages appearing after randomization are based on the number of randomized subjects in each column.

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

**Table 15.2.1.3.2 Analysis Sets and Reasons for Exclusions from Analyses**

Population Sets	THSm2.2 n (%)	mCC n (%)	SA n (%)	Product Test n (%)	Screen Failure n (%)	Overall n (%)
Subjects excluded from PP Set for Period 2						
Has major protocol deviations not compliant	38 (47.5)	0 (0.0)	19 (48.7)			57 (35.6)
Access to medical records were granted for SDV and data entry after withdrawal of PHI authorization	1 (1.3)	0 (0.0)	0 (0.0)			1 (0.6)
Has other major protocol deviations impacting evaluability	4 (5.0)	6 (14.6)	4 (10.3)			14 (8.8)

Note: NA = Not applicable; mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages appearing after randomization are based on the number of randomized subjects in each column.

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Appendix 15.3.1.8 and 15.3.2.3

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**Table 15.2.1.3.2 Analysis Sets and Reasons for Exclusions from Analyses**

Population Sets	THSm2.2 n (%)	mCC n (%)	SA n (%)	Product Test n (%)	Screen Failure n (%)	Overall n (%)
Discontinued in previous period	0 (0.0)	1 (2.4)	5 (12.8)			6 (3.8)
Subjects excluded from PP Set for Period 3						
Has major protocol deviations not compliant	37 (46.3)	0 (0.0)	19 (48.7)			56 (35.0)
Access to medical records were granted for SDV and data entry after withdrawal of PHI authorization	1 (1.3)	0 (0.0)	0 (0.0)			1 (0.6)
Has other major protocol deviations impacting evaluability	4 (5.0)	5 (12.2)	4 (10.3)			13 (8.1)
Discontinued in previous period	1 (1.3)	1 (2.4)	6 (15.4)			8 (5.0)

Note: NA = Not applicable; mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages appearing after randomization are based on the number of randomized subjects in each column.

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

**Table 15.2.1.3.2 Analysis Sets and Reasons for Exclusions from Analyses**

Population Sets	THSm2.2 n (%)	mCC n (%)	SA n (%)	Product Test n (%)	Screen Failure n (%)	Overall n (%)
Subjects excluded from PP Set for Period 4						
Has major protocol deviations not compliant	26 (32.5)	0 (0.0)	22 (56.4)			48 (30.0)
Has other major protocol deviations impacting evaluability	4 (5.0)	5 (12.2)	4 (10.3)			13 (8.1)
Discontinued in previous period	4 (5.0)	4 (9.8)	6 (15.4)			14 (8.8)
Subjects included in Compliant Population						
Period 1	75 (93.8)	35 (85.4)	24 (61.5)			134 (83.8)
Period 2	32 (40.0)	34 (82.9)	8 (20.5)			74 (46.3)
Period 3	36 (45.0)	34 (82.9)	7 (17.9)			77 (48.1)
Period 4	41 (51.3)	31 (75.6)	7 (17.9)			79 (49.4)

Note: NA = Not applicable; mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages appearing after randomization are based on the number of randomized subjects in each column.

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

**Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population**

Variable	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Only (N=5)	Overall Safety (N=165)
Sex						
Male	n (%)	48 (60.0)	24 (58.5)	24 (61.5)	2 (40.0)	98 (59.4)
Female	n (%)	32 (40.0)	17 (41.5)	15 (38.5)	3 (60.0)	67 (40.6)
Age (years)	n	80	41	39	5	165
	Mean (SD)	39.2 (11.72)	33.7 (10.17)	38.8 (11.42)	40.6 (6.95)	37.8 (11.34)
	Median	36.5	32.0	37.0	40.0	35.0
	Min, Max	22, 66	23, 60	22, 58	33, 51	22, 66

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The Overall Safety refers to all subjects in the Safety Population.

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population**

Variable	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Only (N=5)	Overall Safety (N=165)
Race						
White	n (%)	49 (61.3)	28 (68.3)	22 (56.4)	5 (100)	104 (63.0)
Black or African American	n (%)	23 (28.8)	11 (26.8)	17 (43.6)	0	51 (30.9)
American Indian or Alaska Native	n (%)	0	0	0	0	0
Asian	n (%)	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	n (%)	0	0	0	0	0
Other	n (%)	7 (8.8)	2 (4.9)	0	0	9 (5.5)
Missing	n (%)	1 (1.3)	0	0	0	1 (0.6)
Weight (kg)						
	n	79	41	39	4	163
	Mean (SD)	78.92 (13.893)	75.59 (12.710)	76.52 (13.682)	96.68 (15.426)	77.94 (13.862)
	Median	78.60	73.70	74.70	96.10	76.90
	Min, Max	52.9, 115.3	49.3, 103.2	48.1, 121.2	80.5, 114.0	48.1, 121.2

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The Overall Safety refers to all subjects in the Safety Population.

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population**

Variable	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Only (N=5)	Overall Safety (N=165)
Height (m)	n	79	41	39	4	163
	Mean (SD)	1.707 (0.0869)	1.712 (0.0955)	1.707 (0.0890)	1.760 (0.1384)	1.710 (0.0904)
	Median	1.720	1.716	1.713	1.793	1.720
	Min, Max	1.49, 1.84	1.51, 1.89	1.53, 1.89	1.57, 1.89	1.49, 1.89
BMI (kg/m ²)	n	79	41	39	4	163
	Mean (SD)	27.04 (4.105)	25.75 (3.667)	26.20 (3.763)	31.30 (4.646)	26.62 (4.002)
	Median	26.80	25.30	25.60	33.30	26.60
	Min, Max	19.1, 34.9	18.6, 32.9	19.4, 34.3	24.4, 34.2	18.6, 34.9
Underweight	n (%)	0	0	0	0	0
Normal weight	n (%)	26 (32.5)	18 (43.9)	19 (48.7)	1 (20.0)	64 (38.8)
Overweight	n (%)	32 (40.0)	16 (39.0)	13 (33.3)	0	61 (37.0)
Obese	n (%)	21 (26.3)	7 (17.1)	7 (17.9)	3 (60.0)	38 (23.0)
Missing	n (%)	1 (1.3)	0	0	1 (20.0)	2 (1.2)

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The Overall Safety refers to all subjects in the Safety Population.

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population**

Variable	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Only (N=5)	Overall Safety (N=165)
Waist circumference (cm)	n	79	41	39	4	163
	Mean (SD)	95.7 (18.33)	93.8 (20.74)	92.1 (11.57)	96.3 (38.98)	94.4 (18.16)
	Median	94.0	91.0	91.0	108.0	92.0
	Min, Max	28, 167	33, 169	73, 121	42, 127	28, 169
Cigarette consumption						
10-19 cig/day	n (%)	43 (53.8)	21 (51.2)	18 (46.2)	3 (60.0)	85 (51.5)
>19 cig/day	n (%)	36 (45.0)	20 (48.8)	21 (53.8)	1 (20.0)	78 (47.3)
Missing	n (%)	1 (1.3)	0	0	1 (20.0)	2 (1.2)

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The Overall Safety refers to all subjects in the Safety Population.

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population**

Variable	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Only (N=5)	Overall Safety (N=165)
FTND score	n	80	39	39	4	162
	Mean (SD)	5.6 (2.25)	5.5 (1.67)	5.7 (2.14)	4.3 (0.96)	5.6 (2.07)
	Median	6.0	6.0	6.0	4.5	6.0
	Min, Max	0, 10	1, 9	2, 9	3, 5	0, 10
FTND score						
Mild	n (%)	14 (17.5)	4 (9.8)	7 (17.9)	1 (20.0)	26 (15.8)
Moderate	n (%)	35 (43.8)	25 (61.0)	18 (46.2)	3 (60.0)	81 (49.1)
Severe	n (%)	31 (38.8)	10 (24.4)	14 (35.9)	0	55 (33.3)
Missing	n (%)	0	2 (4.9)	0	1 (20.0)	3 (1.8)

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The Overall Safety refers to all subjects in the Safety Population.

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population**

Variable	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Only (N=5)	Overall Safety (N=165)
Individual product preference						
THS 2.2 menthol	n (%)	10 (12.5)	5 (12.2)	11 (28.2)	1 (20.0)	27 (16.4)
mCC	n (%)	40 (50.0)	25 (61.0)	19 (48.7)	1 (20.0)	85 (51.5)
SA	n (%)	2 (2.5)	0	0	0	2 (1.2)
No preference	n (%)	27 (33.8)	11 (26.8)	9 (23.1)	2 (40.0)	49 (29.7)
Missing	n (%)	1 (1.3)	0	0	1 (20.0)	2 (1.2)
Day 4 SES Questionnaire						
SES educational attainment						
Low	n (%)	7 (8.8)	2 (4.9)	5 (12.8)	0	14 (8.5)
Moderate	n (%)	25 (31.3)	12 (29.3)	9 (23.1)	0	46 (27.9)
High	n (%)	47 (58.8)	26 (63.4)	20 (51.3)	0	93 (56.4)
Missing	n (%)	1 (1.3)	1 (2.4)	5 (12.8)	5 (100)	12 (7.3)

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The Overall Safety refers to all subjects in the Safety Population.

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.1 Summary of Demographics and Other Baseline Characteristics - Safety Population**

Variable	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Only (N=5)	Overall Safety (N=165)
SES annual household income						
Low	n (%)	28 (35.0)	18 (43.9)	15 (38.5)	0	61 (37.0)
Moderate	n (%)	21 (26.3)	7 (17.1)	9 (23.1)	0	37 (22.4)
High	n (%)	14 (17.5)	5 (12.2)	6 (15.4)	0	25 (15.2)
Missing	n (%)	17 (21.3)	11 (26.8)	9 (23.1)	5 (100)	42 (25.5)
SES Composite						
Low	n (%)	1 (1.3)	2 (4.9)	2 (5.1)	0	5 (3.0)
Moderate	n (%)	28 (35.0)	16 (39.0)	15 (38.5)	0	59 (35.8)
High	n (%)	34 (42.5)	12 (29.3)	13 (33.3)	0	59 (35.8)
Missing	n (%)	17 (21.3)	11 (26.8)	9 (23.1)	5 (100)	42 (25.5)

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The Overall Safety refers to all subjects in the Safety Population.

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.2 Summary of Demographics and Other Baseline Characteristics - FAS**

Variable	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Sex					
Male	n (%)	48 (60.0)	24 (58.5)	24 (61.5)	96 (60.0)
Female	n (%)	32 (40.0)	17 (41.5)	15 (38.5)	64 (40.0)
Age (years)	n	80	41	39	160
	Mean (SD)	39.2 (11.72)	33.7 (10.17)	38.8 (11.42)	37.7 (11.45)
	Median	36.5	32.0	37.0	34.5
	Min, Max	22, 66	23, 60	22, 58	22, 66

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.2 Summary of Demographics and Other Baseline Characteristics - FAS**

Variable	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Race					
White	n (%)	49 (61.3)	28 (68.3)	22 (56.4)	99 (61.9)
Black or African American	n (%)	23 (28.8)	11 (26.8)	17 (43.6)	51 (31.9)
American Indian or Alaska Native	n (%)	0	0	0	0
Asian	n (%)	0	0	0	0
Native Hawaiian or Other Pacific Islander	n (%)	0	0	0	0
Other	n (%)	7 (8.8)	2 (4.9)	0	9 (5.6)
Missing	n (%)	1 (1.3)	0	0	1 (0.6)
Weight (kg)					
	n	79	41	39	159
	Mean (SD)	78.92 (13.893)	75.59 (12.710)	76.52 (13.682)	77.47 (13.542)
	Median	78.60	73.70	74.70	76.50
	Min, Max	52.9, 115.3	49.3, 103.2	48.1, 121.2	48.1, 121.2

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.2 Summary of Demographics and Other Baseline Characteristics - FAS**

Variable	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Height (m)	n	79	41	39	159
	Mean (SD)	1.707 (0.0869)	1.712 (0.0955)	1.707 (0.0890)	1.709 (0.0892)
	Median	1.720	1.716	1.713	1.716
	Min, Max	1.49, 1.84	1.51, 1.89	1.53, 1.89	1.49, 1.89
BMI (kg/m ²)	n	79	41	39	159
	Mean (SD)	27.04 (4.105)	25.75 (3.667)	26.20 (3.763)	26.50 (3.930)
	Median	26.80	25.30	25.60	26.50
	Min, Max	19.1, 34.9	18.6, 32.9	19.4, 34.3	18.6, 34.9
Underweight	n (%)	0	0	0	0
Normal weight	n (%)	26 (32.5)	18 (43.9)	19 (48.7)	63 (39.4)
Overweight	n (%)	32 (40.0)	16 (39.0)	13 (33.3)	61 (38.1)
Obese	n (%)	21 (26.3)	7 (17.1)	7 (17.9)	35 (21.9)
Missing	n (%)	1 (1.3)	0	0	1 (0.6)

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.2 Summary of Demographics and Other Baseline Characteristics - FAS**

Variable	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Waist circumference (cm)	n	79	41	39	159
	Mean (SD)	95.7 (18.33)	93.8 (20.74)	92.1 (11.57)	94.3 (17.58)
	Median	94.0	91.0	91.0	92.0
	Min, Max	28, 167	33, 169	73, 121	28, 169
Cigarette consumption					
10-19 cig/day	n (%)	43 (53.8)	21 (51.2)	18 (46.2)	82 (51.3)
>19 cig/day	n (%)	36 (45.0)	20 (48.8)	21 (53.8)	77 (48.1)
Missing	n (%)	1 (1.3)	0	0	1 (0.6)

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.2 Summary of Demographics and Other Baseline Characteristics - FAS**

Variable	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
FTND score	n	80	39	39	158
	Mean (SD)	5.6 (2.25)	5.5 (1.67)	5.7 (2.14)	5.6 (2.08)
	Median	6.0	6.0	6.0	6.0
	Min, Max	0, 10	1, 9	2, 9	0, 10
FTND score					
Mild	n (%)	14 (17.5)	4 (9.8)	7 (17.9)	25 (15.6)
Moderate	n (%)	35 (43.8)	25 (61.0)	18 (46.2)	78 (48.8)
Severe	n (%)	31 (38.8)	10 (24.4)	14 (35.9)	55 (34.4)
Missing	n (%)	0	2 (4.9)	0	2 (1.3)

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.2 Summary of Demographics and Other Baseline Characteristics - FAS**

Variable	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Individual product preference					
THS 2.2 menthol	n (%)	10 (12.5)	5 (12.2)	11 (28.2)	26 (16.3)
mCC	n (%)	40 (50.0)	25 (61.0)	19 (48.7)	84 (52.5)
SA	n (%)	2 (2.5)	0	0	2 (1.3)
No preference	n (%)	27 (33.8)	11 (26.8)	9 (23.1)	47 (29.4)
Missing	n (%)	1 (1.3)	0	0	1 (0.6)
Day 4 SES Questionnaire					
SES educational attainment					
Low	n (%)	7 (8.8)	2 (4.9)	5 (12.8)	14 (8.8)
Moderate	n (%)	25 (31.3)	12 (29.3)	9 (23.1)	46 (28.8)
High	n (%)	47 (58.8)	26 (63.4)	20 (51.3)	93 (58.1)
Missing	n (%)	1 (1.3)	1 (2.4)	5 (12.8)	7 (4.4)

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.2 Summary of Demographics and Other Baseline Characteristics - FAS**

Variable	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
SES annual household income					
Low	n (%)	28 (35.0)	18 (43.9)	15 (38.5)	61 (38.1)
Moderate	n (%)	21 (26.3)	7 (17.1)	9 (23.1)	37 (23.1)
High	n (%)	14 (17.5)	5 (12.2)	6 (15.4)	25 (15.6)
Missing	n (%)	17 (21.3)	11 (26.8)	9 (23.1)	37 (23.1)
SES Composite					
Low	n (%)	1 (1.3)	2 (4.9)	2 (5.1)	5 (3.1)
Moderate	n (%)	28 (35.0)	16 (39.0)	15 (38.5)	59 (36.9)
High	n (%)	34 (42.5)	12 (29.3)	13 (33.3)	59 (36.9)
Missing	n (%)	17 (21.3)	11 (26.8)	9 (23.1)	37 (23.1)

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
Sex					
Male	n (%)	46 (61.3)	20 (57.1)	15 (62.5)	81 (60.4)
Female	n (%)	29 (38.7)	15 (42.9)	9 (37.5)	53 (39.6)
Age (years)	n	75	35	24	134
	Mean (SD)	39.0 (11.77)	34.1 (10.48)	40.5 (10.79)	38.0 (11.45)
	Median	36.0	32.0	40.0	34.5
	Min, Max	22, 66	23, 60	22, 57	22, 66

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
Race					
White	n (%)	46 (61.3)	24 (68.6)	13 (54.2)	83 (61.9)
Black or African American	n (%)	22 (29.3)	10 (28.6)	11 (45.8)	43 (32.1)
American Indian or Alaska Native	n (%)	0	0	0	0
Asian	n (%)	0	0	0	0
Native Hawaiian or Other Pacific Islander	n (%)	0	0	0	0
Other	n (%)	7 (9.3)	1 (2.9)	0	8 (6.0)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
Weight (kg)	n	75	35	24	134
	Mean (SD)	79.42 (13.858)	76.58 (13.148)	75.18 (11.197)	77.92 (13.260)
	Median	78.70	75.40	74.10	77.15
	Min, Max	52.9, 115.3	49.3, 103.2	48.1, 97.1	48.1, 115.3
Height (m)	n	75	35	24	134
	Mean (SD)	1.708 (0.0867)	1.714 (0.0998)	1.707 (0.0882)	1.709 (0.0899)
	Median	1.726	1.720	1.739	1.720
	Min, Max	1.49, 1.84	1.51, 1.89	1.53, 1.85	1.49, 1.89

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
BMI (kg/m ²)	n	75	35	24	134
	Mean (SD)	27.19 (4.136)	26.06 (3.805)	25.79 (3.240)	26.65 (3.928)
	Median	27.10	26.10	24.60	26.70
	Min, Max	19.1, 34.9	18.6, 32.9	20.6, 32.0	18.6, 34.9
Underweight	n (%)	0	0	0	0
Normal weight	n (%)	24 (32.0)	15 (42.9)	13 (54.2)	52 (38.8)
Overweight	n (%)	30 (40.0)	13 (37.1)	8 (33.3)	51 (38.1)
Obese	n (%)	21 (28.0)	7 (20.0)	3 (12.5)	31 (23.1)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
Waist circumference (cm)	n	75	35	24	134
	Mean (SD)	96.1 (18.63)	96.7 (19.27)	92.3 (10.13)	95.6 (17.56)
	Median	94.0	92.0	91.5	92.0
	Min, Max	28, 167	77, 169	73, 109	28, 169
Cigarette consumption					
10-19 cig/day	n (%)	43 (57.3)	20 (57.1)	13 (54.2)	76 (56.7)
>19 cig/day	n (%)	32 (42.7)	15 (42.9)	11 (45.8)	58 (43.3)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
FTND score	n	75	34	24	133
	Mean (SD)	5.7 (2.26)	5.5 (1.71)	5.5 (2.03)	5.6 (2.08)
	Median	6.0	6.0	6.0	6.0
	Min, Max	0, 10	1, 9	2, 8	0, 10
FTND score					
Mild	n (%)	13 (17.3)	4 (11.4)	5 (20.8)	22 (16.4)
Moderate	n (%)	31 (41.3)	21 (60.0)	11 (45.8)	63 (47.0)
Severe	n (%)	31 (41.3)	9 (25.7)	8 (33.3)	48 (35.8)
Missing	n (%)	0	1 (2.9)	0	1 (0.7)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
Individual product preference					
THS 2.2 menthol	n (%)	10 (13.3)	4 (11.4)	9 (37.5)	23 (17.2)
mCC	n (%)	37 (49.3)	22 (62.9)	10 (41.7)	69 (51.5)
SA	n (%)	2 (2.7)	0	0	2 (1.5)
No preference	n (%)	26 (34.7)	9 (25.7)	5 (20.8)	40 (29.9)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
Day 4 SES Questionnaire					
SES educational attainment					
Low	n (%)	6 (8.0)	0	2 (8.3)	8 (6.0)
Moderate	n (%)	24 (32.0)	12 (34.3)	7 (29.2)	43 (32.1)
High	n (%)	45 (60.0)	22 (62.9)	15 (62.5)	82 (61.2)
Missing	n (%)	0	1 (2.9)	0	1 (0.7)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
SES annual household income					
Low	n (%)	26 (34.7)	14 (40.0)	9 (37.5)	49 (36.6)
Moderate	n (%)	20 (26.7)	7 (20.0)	6 (25.0)	33 (24.6)
High	n (%)	13 (17.3)	4 (11.4)	6 (25.0)	23 (17.2)
Missing	n (%)	16 (21.3)	10 (28.6)	3 (12.5)	29 (21.6)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
SES Composite					
Low	n (%)	0	0	0	0
Moderate	n (%)	27 (36.0)	14 (40.0)	10 (41.7)	51 (38.1)
High	n (%)	32 (42.7)	11 (31.4)	11 (45.8)	54 (40.3)
Missing	n (%)	16 (21.3)	10 (28.6)	3 (12.5)	29 (21.6)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)	Overall PP Set (N=87)
Sex					
Male	n (%)	24 (60.0)	21 (61.8)	8 (61.5)	53 (60.9)
Female	n (%)	16 (40.0)	13 (38.2)	5 (38.5)	34 (39.1)
Age (years)	n	40	34	13	87
	Mean (SD)	38.9 (11.92)	33.4 (10.39)	40.2 (11.06)	36.9 (11.45)
	Median	34.5	31.0	38.0	33.0
	Min, Max	24, 66	23, 60	22, 54	22, 66

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)	Overall PP Set (N=87)
Race					
White	n (%)	30 (75.0)	22 (64.7)	5 (38.5)	57 (65.5)
Black or African American	n (%)	10 (25.0)	11 (32.4)	8 (61.5)	29 (33.3)
American Indian or Alaska Native	n (%)	0	0	0	0
Asian	n (%)	0	0	0	0
Native Hawaiian or Other Pacific Islander	n (%)	0	0	0	0
Other	n (%)	0	1 (2.9)	0	1 (1.1)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)	Overall PP Set (N=87)
Weight (kg)	n	40	34	13	87
	Mean (SD)	78.82 (14.583)	77.02 (13.077)	70.55 (10.279)	76.88 (13.588)
	Median	79.35	76.15	72.70	76.90
	Min, Max	52.9, 108.7	49.3, 103.2	48.1, 87.7	48.1, 108.7
Height (m)	n	40	34	13	87
	Mean (SD)	1.699 (0.0915)	1.721 (0.0934)	1.698 (0.0858)	1.708 (0.0910)
	Median	1.700	1.720	1.713	1.713
	Min, Max	1.49, 1.84	1.53, 1.89	1.53, 1.83	1.49, 1.89

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)	Overall PP Set (N=87)
BMI (kg/m ²)	n	40	34	13	87
	Mean (SD)	27.26 (4.353)	25.98 (3.770)	24.48 (3.249)	26.34 (4.061)
	Median	27.15	25.80	24.20	26.60
	Min, Max	19.1, 34.4	18.6, 32.9	19.4, 30.0	18.6, 34.4
Underweight	n (%)	0	0	0	0
Normal weight	n (%)	11 (27.5)	14 (41.2)	8 (61.5)	33 (37.9)
Overweight	n (%)	17 (42.5)	14 (41.2)	4 (30.8)	35 (40.2)
Obese	n (%)	12 (30.0)	6 (17.6)	1 (7.7)	19 (21.8)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)	Overall PP Set (N=87)
Waist circumference (cm)	n	40	34	13	87
	Mean (SD)	95.9 (15.21)	96.9 (19.42)	87.1 (11.58)	95.0 (16.72)
	Median	95.5	91.5	85.0	92.0
	Min, Max	73, 149	80, 169	73, 106	73, 169
Cigarette consumption					
10-19 cig/day	n (%)	18 (45.0)	19 (55.9)	7 (53.8)	44 (50.6)
>19 cig/day	n (%)	22 (55.0)	15 (44.1)	6 (46.2)	43 (49.4)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)	Overall PP Set (N=87)
FTND score	n	40	33	13	86
	Mean (SD)	6.1 (2.11)	5.6 (1.72)	6.7 (1.66)	6.0 (1.92)
	Median	6.5	6.0	7.0	6.0
	Min, Max	1, 10	1, 9	3, 8	1, 10
FTND score					
Mild	n (%)	4 (10.0)	4 (11.8)	1 (7.7)	9 (10.3)
Moderate	n (%)	16 (40.0)	20 (58.8)	4 (30.8)	40 (46.0)
Severe	n (%)	20 (50.0)	9 (26.5)	8 (61.5)	37 (42.5)
Missing	n (%)	0	1 (2.9)	0	1 (1.1)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)	Overall PP Set (N=87)
Individual product preference					
THS 2.2 menthol	n (%)	9 (22.5)	4 (11.8)	2 (15.4)	15 (17.2)
mCC	n (%)	19 (47.5)	21 (61.8)	8 (61.5)	48 (55.2)
SA	n (%)	2 (5.0)	0	0	2 (2.3)
No preference	n (%)	10 (25.0)	9 (26.5)	3 (23.1)	22 (25.3)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)	Overall PP Set (N=87)
Day 4 SES Questionnaire					
SES educational attainment					
Low	n (%)	5 (12.5)	0	2 (15.4)	7 (8.0)
Moderate	n (%)	12 (30.0)	11 (32.4)	5 (38.5)	28 (32.2)
High	n (%)	23 (57.5)	23 (67.6)	6 (46.2)	52 (59.8)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)	Overall PP Set (N=87)
SES annual household income					
Low	n (%)	16 (40.0)	14 (41.2)	10 (76.9)	40 (46.0)
Moderate	n (%)	9 (22.5)	7 (20.6)	1 (7.7)	17 (19.5)
High	n (%)	7 (17.5)	4 (11.8)	1 (7.7)	12 (13.8)
Missing	n (%)	8 (20.0)	9 (26.5)	1 (7.7)	18 (20.7)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)	Overall PP Set (N=87)
SES Composite					
Low	n (%)	0	0	1 (7.7)	1 (1.1)
Moderate	n (%)	16 (40.0)	14 (41.2)	9 (69.2)	39 (44.8)
High	n (%)	16 (40.0)	11 (32.4)	2 (15.4)	29 (33.3)
Missing	n (%)	8 (20.0)	9 (26.5)	1 (7.7)	18 (20.7)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)	Overall PP Set (N=86)
Sex					
Male	n (%)	23 (59.0)	21 (60.0)	9 (75.0)	53 (61.6)
Female	n (%)	16 (41.0)	14 (40.0)	3 (25.0)	33 (38.4)
Age (years)	n	39	35	12	86
	Mean (SD)	38.8 (12.05)	33.3 (10.24)	41.3 (9.87)	36.9 (11.35)
	Median	34.0	32.0	40.5	33.0
	Min, Max	24, 66	23, 60	26, 54	23, 66

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)	Overall PP Set (N=86)
Race					
White	n (%)	29 (74.4)	23 (65.7)	5 (41.7)	57 (66.3)
Black or African American	n (%)	9 (23.1)	11 (31.4)	7 (58.3)	27 (31.4)
American Indian or Alaska Native	n (%)	0	0	0	0
Asian	n (%)	0	0	0	0
Native Hawaiian or Other Pacific Islander	n (%)	0	0	0	0
Other	n (%)	1 (2.6)	1 (2.9)	0	2 (2.3)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)	Overall PP Set (N=86)
Weight (kg)	n	39	35	12	86
	Mean (SD)	80.57 (15.677)	76.57 (13.155)	70.78 (11.306)	77.57 (14.376)
	Median	83.00	75.40	71.70	77.45
	Min, Max	52.9, 115.3	49.3, 103.2	48.1, 87.7	48.1, 115.3
Height (m)	n	39	35	12	86
	Mean (SD)	1.700 (0.0913)	1.718 (0.0939)	1.712 (0.0891)	1.709 (0.0914)
	Median	1.700	1.720	1.739	1.716
	Min, Max	1.49, 1.84	1.53, 1.89	1.53, 1.83	1.49, 1.89

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)	Overall PP Set (N=86)
BMI (kg/m ²)	n	39	35	12	86
	Mean (SD)	27.79 (4.542)	25.91 (3.736)	24.11 (3.145)	26.51 (4.219)
	Median	27.60	25.50	23.55	26.50
	Min, Max	19.1, 34.9	18.6, 32.9	19.4, 30.0	18.6, 34.9
Underweight	n (%)	0	0	0	0
Normal weight	n (%)	10 (25.6)	15 (42.9)	8 (66.7)	33 (38.4)
Overweight	n (%)	15 (38.5)	14 (40.0)	3 (25.0)	32 (37.2)
Obese	n (%)	14 (35.9)	6 (17.1)	1 (8.3)	21 (24.4)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)	Overall PP Set (N=86)
Waist circumference (cm)	n	39	35	12	86
	Mean (SD)	97.8 (15.33)	96.3 (19.43)	86.0 (10.83)	95.6 (16.93)
	Median	98.0	91.0	83.0	92.0
	Min, Max	73, 149	77, 169	73, 106	73, 169
Cigarette consumption					
10-19 cig/day	n (%)	16 (41.0)	20 (57.1)	8 (66.7)	44 (51.2)
>19 cig/day	n (%)	23 (59.0)	15 (42.9)	4 (33.3)	42 (48.8)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)	Overall PP Set (N=86)
FTND score	n	39	34	12	85
	Mean (SD)	5.9 (2.12)	5.5 (1.71)	5.8 (2.42)	5.7 (2.00)
	Median	6.0	6.0	6.0	6.0
	Min, Max	1, 10	1, 9	2, 8	1, 10
FTND score					
Mild	n (%)	4 (10.3)	4 (11.4)	3 (25.0)	11 (12.8)
Moderate	n (%)	17 (43.6)	21 (60.0)	4 (33.3)	42 (48.8)
Severe	n (%)	18 (46.2)	9 (25.7)	5 (41.7)	32 (37.2)
Missing	n (%)	0	1 (2.9)	0	1 (1.2)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)	Overall PP Set (N=86)
Individual product preference					
THS 2.2 menthol	n (%)	6 (15.4)	4 (11.4)	2 (16.7)	12 (14.0)
mCC	n (%)	18 (46.2)	22 (62.9)	8 (66.7)	48 (55.8)
SA	n (%)	2 (5.1)	0	0	2 (2.3)
No preference	n (%)	13 (33.3)	9 (25.7)	2 (16.7)	24 (27.9)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)	Overall PP Set (N=86)
Day 4 SES Questionnaire					
SES educational attainment					
Low	n (%)	5 (12.8)	0	1 (8.3)	6 (7.0)
Moderate	n (%)	10 (25.6)	12 (34.3)	5 (41.7)	27 (31.4)
High	n (%)	24 (61.5)	23 (65.7)	6 (50.0)	53 (61.6)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)	Overall PP Set (N=86)
SES annual household income					
Low	n (%)	13 (33.3)	15 (42.9)	9 (75.0)	37 (43.0)
Moderate	n (%)	8 (20.5)	7 (20.0)	0	15 (17.4)
High	n (%)	8 (20.5)	4 (11.4)	3 (25.0)	15 (17.4)
Missing	n (%)	10 (25.6)	9 (25.7)	0	19 (22.1)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)	Overall PP Set (N=86)
SES Composite					
Low	n (%)	0	0	1 (8.3)	1 (1.2)
Moderate	n (%)	13 (33.3)	15 (42.9)	8 (66.7)	36 (41.9)
High	n (%)	16 (41.0)	11 (31.4)	3 (25.0)	30 (34.9)
Missing	n (%)	10 (25.6)	9 (25.7)	0	19 (22.1)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)	Overall PP Set (N=88)
Sex					
Male	n (%)	28 (59.6)	19 (59.4)	7 (77.8)	54 (61.4)
Female	n (%)	19 (40.4)	13 (40.6)	2 (22.2)	34 (38.6)
Age (years)	n	47	32	9	88
	Mean (SD)	37.6 (11.92)	34.0 (10.43)	40.7 (10.79)	36.6 (11.37)
	Median	33.0	32.0	38.0	33.0
	Min, Max	24, 66	23, 60	26, 54	23, 66

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)	Overall PP Set (N=88)
Race					
White	n (%)	34 (72.3)	20 (62.5)	4 (44.4)	58 (65.9)
Black or African American	n (%)	10 (21.3)	11 (34.4)	5 (55.6)	26 (29.5)
American Indian or Alaska Native	n (%)	0	0	0	0
Asian	n (%)	0	0	0	0
Native Hawaiian or Other Pacific Islander	n (%)	0	0	0	0
Other	n (%)	3 (6.4)	1 (3.1)	0	4 (4.5)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)	Overall PP Set (N=88)
Weight (kg)	n	47	32	9	88
	Mean (SD)	78.94 (14.966)	77.64 (13.191)	67.97 (11.177)	77.35 (14.228)
	Median	78.80	77.70	68.40	77.15
	Min, Max	52.9, 115.3	49.3, 103.2	48.1, 85.8	48.1, 115.3
Height (m)	n	47	32	9	88
	Mean (SD)	1.702 (0.0900)	1.723 (0.0932)	1.713 (0.0946)	1.711 (0.0911)
	Median	1.709	1.720	1.737	1.716
	Min, Max	1.49, 1.84	1.53, 1.89	1.53, 1.83	1.49, 1.89

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)	Overall PP Set (N=88)
BMI (kg/m ²)	n	47	32	9	88
	Mean (SD)	27.23 (4.502)	26.11 (3.717)	23.07 (2.515)	26.39 (4.215)
	Median	27.10	25.80	23.10	26.55
	Min, Max	19.1, 34.9	18.6, 32.9	19.4, 27.1	18.6, 34.9
Underweight	n (%)	0	0	0	0
Normal weight	n (%)	13 (27.7)	13 (40.6)	7 (77.8)	33 (37.5)
Overweight	n (%)	20 (42.6)	13 (40.6)	2 (22.2)	35 (39.8)
Obese	n (%)	14 (29.8)	6 (18.8)	0	20 (22.7)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)	Overall PP Set (N=88)
Waist circumference (cm)	n	47	32	9	88
	Mean (SD)	95.8 (14.89)	97.2 (20.08)	81.9 (8.53)	94.9 (16.95)
	Median	94.0	91.5	81.0	92.0
	Min, Max	73, 149	77, 169	73, 98	73, 169
Cigarette consumption					
10-19 cig/day	n (%)	21 (44.7)	19 (59.4)	6 (66.7)	46 (52.3)
>19 cig/day	n (%)	26 (55.3)	13 (40.6)	3 (33.3)	42 (47.7)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)	Overall PP Set (N=88)
FTND score	n	47	32	9	88
	Mean (SD)	5.8 (2.22)	5.6 (1.70)	5.9 (2.37)	5.8 (2.04)
	Median	6.0	6.0	6.0	6.0
	Min, Max	1, 10	1, 9	2, 8	1, 10
FTND score					
Mild	n (%)	7 (14.9)	3 (9.4)	2 (22.2)	12 (13.6)
Moderate	n (%)	19 (40.4)	20 (62.5)	3 (33.3)	42 (47.7)
Severe	n (%)	21 (44.7)	9 (28.1)	4 (44.4)	34 (38.6)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)	Overall PP Set (N=88)
Individual product preference					
THS 2.2 menthol	n (%)	7 (14.9)	3 (9.4)	2 (22.2)	12 (13.6)
mCC	n (%)	23 (48.9)	21 (65.6)	5 (55.6)	49 (55.7)
SA	n (%)	2 (4.3)	0	0	2 (2.3)
No preference	n (%)	15 (31.9)	8 (25.0)	2 (22.2)	25 (28.4)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)	Overall PP Set (N=88)
Day 4 SES Questionnaire					
SES educational attainment					
Low	n (%)	5 (10.6)	0	1 (11.1)	6 (6.8)
Moderate	n (%)	15 (31.9)	9 (28.1)	4 (44.4)	28 (31.8)
High	n (%)	27 (57.4)	23 (71.9)	4 (44.4)	54 (61.4)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)	Overall PP Set (N=88)
SES annual household income					
Low	n (%)	20 (42.6)	13 (40.6)	7 (77.8)	40 (45.5)
Moderate	n (%)	9 (19.1)	7 (21.9)	0	16 (18.2)
High	n (%)	8 (17.0)	4 (12.5)	2 (22.2)	14 (15.9)
Missing	n (%)	10 (21.3)	8 (25.0)	0	18 (20.5)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

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**Table 15.2.1.4.3 Summary of Demographics and Other Baseline Characteristics - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)	Overall PP Set (N=88)
SES Composite					
Low	n (%)	0	0	1 (11.1)	1 (1.1)
Moderate	n (%)	20 (42.6)	13 (40.6)	6 (66.7)	39 (44.3)
High	n (%)	17 (36.2)	11 (34.4)	2 (22.2)	30 (34.1)
Missing	n (%)	10 (21.3)	8 (25.0)	0	18 (20.5)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
		Male	Female	Male	Female	Male	Female	Male	Female
Age (years)	n	46	29	20	15	15	9	81	53
	Mean (SD)	38.0 (11.32)	40.7 (12.47)	33.0 (10.58)	35.6 (10.51)	38.3 (9.40)	44.3 (12.40)	36.8 (10.91)	39.9 (12.09)
	Median	33.0	42.0	31.5	32.0	38.0	51.0	34.0	35.0
	Min, Max	22, 66	24, 64	23, 60	23, 55	26, 54	22, 57	22, 66	22, 64

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 1**

		THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
Race									
White	n (%)	27 (36.0)	19 (25.3)	12 (34.3)	12 (34.3)	6 (25.0)	7 (29.2)	45 (33.6)	38 (28.4)
Black or African American	n (%)	15 (20.0)	7 (9.3)	8 (22.9)	2 (5.7)	9 (37.5)	2 (8.3)	32 (23.9)	11 (8.2)
American Indian or Alaska Native	n (%)	0	0	0	0	0	0	0	0
Asian	n (%)	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	n (%)	0	0	0	0	0	0	0	0
Other	n (%)	4 (5.3)	3 (4.0)	0	1 (2.9)	0	0	4 (3.0)	4 (3.0)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
		Male	Female	Male	Female	Male	Female	Male	Female
Weight (kg)	n	46	29	20	15	15	9	81	53
	Mean (SD)	82.29 (13.749)	74.87 (12.992)	78.70 (13.460)	73.75 (12.608)	78.74 (10.365)	69.24 (10.443)	80.74 (13.089)	73.60 (12.436)
	Median	80.65	74.40	79.40	73.60	76.40	70.30	78.80	73.60
	Min, Max	54.6, 115.3	52.9, 105.9	60.9, 103.2	49.3, 97.3	59.5, 97.1	48.1, 81.8	54.6, 115.3	48.1, 105.9
Height (m)	n	46	29	20	15	15	9	81	53
	Mean (SD)	1.759 (0.0533)	1.627 (0.0646)	1.773 (0.0695)	1.634 (0.0762)	1.766 (0.0435)	1.609 (0.0428)	1.764 (0.0558)	1.626 (0.0645)
	Median	1.769	1.626	1.779	1.616	1.756	1.608	1.770	1.617
	Min, Max	1.65, 1.84	1.49, 1.75	1.61, 1.89	1.51, 1.78	1.69, 1.85	1.53, 1.68	1.61, 1.89	1.49, 1.78

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
		Male	Female	Male	Female	Male	Female	Male	Female
BMI (kg/m ²)	n	46	29	20	15	15	9	81	53
	Mean (SD)	26.54 (3.989)	28.23 (4.223)	24.95 (3.502)	27.54 (3.797)	25.25 (3.067)	26.68 (3.505)	25.91 (3.748)	27.77 (3.964)
	Median	26.65	27.10	24.15	28.00	24.20	27.30	26.10	28.00
	Min, Max	19.1, 34.1	20.6, 34.9	20.0, 31.4	18.6, 32.9	21.0, 31.5	20.6, 32.0	19.1, 34.1	18.6, 34.9
Underweight	n (%)	0	0	0	0	0	0	0	0
Normal weight	n (%)	17 (22.7)	7 (9.3)	11 (31.4)	4 (11.4)	9 (37.5)	4 (16.7)	37 (27.6)	15 (11.2)
Overweight	n (%)	20 (26.7)	10 (13.3)	6 (17.1)	7 (20.0)	5 (20.8)	3 (12.5)	31 (23.1)	20 (14.9)
Obese	n (%)	9 (12.0)	12 (16.0)	3 (8.6)	4 (11.4)	1 (4.2)	2 (8.3)	13 (9.7)	18 (13.4)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
		Male	Female	Male	Female	Male	Female	Male	Female
Waist circumference (cm)	n	46	29	20	15	15	9	81	53
	Mean (SD)	93.8 (9.94)	99.8 (27.13)	91.1 (9.05)	104.2 (26.17)	92.0 (10.58)	92.7 (9.94)	92.8 (9.80)	99.8 (24.71)
	Median	94.0	96.0	89.0	94.0	91.0	92.0	92.0	94.0
	Min, Max	73, 113	28, 167	80, 110	77, 169	76, 109	73, 104	73, 113	28, 169
Cigarette consumption									
10-19 cig/day	n (%)	31 (41.3)	12 (16.0)	14 (40.0)	6 (17.1)	10 (41.7)	3 (12.5)	55 (41.0)	21 (15.7)
>19 cig/day	n (%)	15 (20.0)	17 (22.7)	6 (17.1)	9 (25.7)	5 (20.8)	6 (25.0)	26 (19.4)	32 (23.9)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
		Male	Female	Male	Female	Male	Female	Male	Female
FTND score	n	46	29	19	15	15	9	80	53
	Mean (SD)	5.3 (2.21)	6.2 (2.28)	5.3 (1.86)	5.8 (1.53)	5.1 (1.99)	6.3 (1.94)	5.3 (2.07)	6.1 (2.01)
	Median	6.0	6.0	5.0	6.0	6.0	7.0	6.0	6.0
	Min, Max	0, 9	1, 10	1, 9	3, 8	2, 8	2, 8	0, 9	1, 10
FTND score									
Mild	n (%)	10 (13.3)	3 (4.0)	3 (8.6)	1 (2.9)	4 (16.7)	1 (4.2)	17 (12.7)	5 (3.7)
Moderate	n (%)	19 (25.3)	12 (16.0)	12 (34.3)	9 (25.7)	8 (33.3)	3 (12.5)	39 (29.1)	24 (17.9)
Severe	n (%)	17 (22.7)	14 (18.7)	4 (11.4)	5 (14.3)	3 (12.5)	5 (20.8)	24 (17.9)	24 (17.9)
Missing	n (%)	0	0	1 (2.9)	0	0	0	1 (0.7)	0

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 1**

		THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
Individual product preference									
THS 2.2 menthol	n (%)	9 (12.0)	1 (1.3)	3 (8.6)	1 (2.9)	7 (29.2)	2 (8.3)	19 (14.2)	4 (3.0)
mCC	n (%)	22 (29.3)	15 (20.0)	10 (28.6)	12 (34.3)	6 (25.0)	4 (16.7)	38 (28.4)	31 (23.1)
SA	n (%)	0	2 (2.7)	0	0	0	0	0	2 (1.5)
No preference	n (%)	15 (20.0)	11 (14.7)	7 (20.0)	2 (5.7)	2 (8.3)	3 (12.5)	24 (17.9)	16 (11.9)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 1**

		THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
Day 4 SES Questionnaire									
SES educational attainment									
Low	n (%)	2 (2.7)	4 (5.3)	0	0	1 (4.2)	1 (4.2)	3 (2.2)	5 (3.7)
Moderate	n (%)	17 (22.7)	7 (9.3)	9 (25.7)	3 (8.6)	5 (20.8)	2 (8.3)	31 (23.1)	12 (9.0)
High	n (%)	27 (36.0)	18 (24.0)	11 (31.4)	11 (31.4)	9 (37.5)	6 (25.0)	47 (35.1)	35 (26.1)
Missing	n (%)	0	0	0	1 (2.9)	0	0	0	1 (0.7)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 1**

		THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
SES annual household income									
Low	n (%)	19 (25.3)	7 (9.3)	10 (28.6)	4 (11.4)	5 (20.8)	4 (16.7)	34 (25.4)	15 (11.2)
Moderate	n (%)	12 (16.0)	8 (10.7)	3 (8.6)	4 (11.4)	4 (16.7)	2 (8.3)	19 (14.2)	14 (10.4)
High	n (%)	6 (8.0)	7 (9.3)	2 (5.7)	2 (5.7)	4 (16.7)	2 (8.3)	12 (9.0)	11 (8.2)
Missing	n (%)	9 (12.0)	7 (9.3)	5 (14.3)	5 (14.3)	2 (8.3)	1 (4.2)	16 (11.9)	13 (9.7)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
		Male	Female	Male	Female	Male	Female	Male	Female
SES Composite									
Low	n (%)	0	0	0	0	0	0	0	0
Moderate	n (%)	19 (25.3)	8 (10.7)	10 (28.6)	4 (11.4)	6 (25.0)	4 (16.7)	35 (26.1)	16 (11.9)
High	n (%)	18 (24.0)	14 (18.7)	5 (14.3)	6 (17.1)	7 (29.2)	4 (16.7)	30 (22.4)	24 (17.9)
Missing	n (%)	9 (12.0)	7 (9.3)	5 (14.3)	5 (14.3)	2 (8.3)	1 (4.2)	16 (11.9)	13 (9.7)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
		Male	Female	Male	Female	Male	Female	Male	Female
Age (years)	n	24	16	21	13	8	5	53	34
	Mean (SD)	36.7 (11.57)	42.2 (12.02)	32.5 (10.50)	34.8 (10.48)	36.4 (7.84)	46.2 (13.60)	35.0 (10.67)	39.9 (12.12)
	Median	32.0	42.0	30.0	32.0	37.0	51.0	32.0	36.5
	Min, Max	25, 66	24, 64	23, 60	23, 55	26, 50	22, 54	23, 66	22, 64

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 2**

		THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
Race									
White	n (%)	18 (45.0)	12 (30.0)	12 (35.3)	10 (29.4)	1 (7.7)	4 (30.8)	31 (35.6)	26 (29.9)
Black or African American	n (%)	6 (15.0)	4 (10.0)	9 (26.5)	2 (5.9)	7 (53.8)	1 (7.7)	22 (25.3)	7 (8.0)
American Indian or Alaska Native	n (%)	0	0	0	0	0	0	0	0
Asian	n (%)	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	n (%)	0	0	0	0	0	0	0	0
Other	n (%)	0	0	0	1 (2.9)	0	0	0	1 (1.1)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
		Male	Female	Male	Female	Male	Female	Male	Female
Weight (kg)	n	24	16	21	13	8	5	53	34
	Mean (SD)	81.57 (14.782)	74.69 (13.696)	78.23 (13.296)	75.06 (12.998)	71.96 (8.922)	68.28 (12.932)	78.80 (13.647)	73.89 (13.138)
	Median	82.20	74.30	78.50	73.70	72.25	72.70	78.50	73.85
	Min, Max	54.6, 108.7	52.9, 96.2	60.9, 103.2	49.3, 97.3	59.5, 87.7	48.1, 79.7	54.6, 108.7	48.1, 97.3
Height (m)	n	24	16	21	13	8	5	53	34
	Mean (SD)	1.753 (0.0586)	1.618 (0.0695)	1.768 (0.0725)	1.646 (0.0728)	1.753 (0.0443)	1.610 (0.0532)	1.759 (0.0621)	1.627 (0.0684)
	Median	1.769	1.625	1.778	1.627	1.750	1.608	1.769	1.624
	Min, Max	1.65, 1.84	1.49, 1.73	1.61, 1.89	1.53, 1.78	1.69, 1.83	1.53, 1.68	1.61, 1.89	1.49, 1.78

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
		Male	Female	Male	Female	Male	Female	Male	Female
BMI (kg/m ²)	n	24	16	21	13	8	5	53	34
	Mean (SD)	26.48 (4.227)	28.44 (4.405)	24.96 (3.413)	27.63 (3.858)	23.41 (2.636)	26.18 (3.689)	25.41 (3.814)	27.80 (4.061)
	Median	27.20	26.95	24.80	28.00	23.15	27.30	25.30	27.65
	Min, Max	19.1, 33.3	20.6, 34.4	20.0, 31.4	18.6, 32.9	19.4, 27.8	20.6, 30.0	19.1, 33.3	18.6, 34.4
Underweight	n (%)	0	0	0	0	0	0	0	0
Normal weight	n (%)	8 (20.0)	3 (7.5)	11 (32.4)	3 (8.8)	6 (46.2)	2 (15.4)	25 (28.7)	8 (9.2)
Overweight	n (%)	11 (27.5)	6 (15.0)	7 (20.6)	7 (20.6)	2 (15.4)	2 (15.4)	20 (23.0)	15 (17.2)
Obese	n (%)	5 (12.5)	7 (17.5)	3 (8.8)	3 (8.8)	0	1 (7.7)	8 (9.2)	11 (12.6)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
		Male	Female	Male	Female	Male	Female	Male	Female
Waist circumference (cm)	n	24	16	21	13	8	5	53	34
	Mean (SD)	93.6 (11.28)	99.4 (19.61)	90.6 (9.04)	107.1 (26.83)	83.3 (10.17)	93.2 (12.05)	90.8 (10.68)	101.4 (21.89)
	Median	96.0	95.5	87.0	97.0	81.0	97.0	89.0	97.0
	Min, Max	73, 110	76, 149	80, 110	83, 169	73, 106	73, 103	73, 110	73, 169
Cigarette consumption									
10-19 cig/day	n (%)	14 (35.0)	4 (10.0)	14 (41.2)	5 (14.7)	6 (46.2)	1 (7.7)	34 (39.1)	10 (11.5)
>19 cig/day	n (%)	10 (25.0)	12 (30.0)	7 (20.6)	8 (23.5)	2 (15.4)	4 (30.8)	19 (21.8)	24 (27.6)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
		Male	Female	Male	Female	Male	Female	Male	Female
FTND score	n	24	16	20	13	8	5	52	34
	Mean (SD)	5.8 (1.99)	6.6 (2.25)	5.3 (1.81)	6.0 (1.53)	6.3 (1.91)	7.4 (0.90)	5.7 (1.90)	6.5 (1.87)
	Median	6.0	7.0	5.0	6.0	6.5	8.0	6.0	7.0
	Min, Max	1, 9	2, 10	1, 9	3, 8	3, 8	6, 8	1, 9	2, 10
FTND score									
Mild	n (%)	3 (7.5)	1 (2.5)	3 (8.8)	1 (2.9)	1 (7.7)	0	7 (8.0)	2 (2.3)
Moderate	n (%)	10 (25.0)	6 (15.0)	13 (38.2)	7 (20.6)	3 (23.1)	1 (7.7)	26 (29.9)	14 (16.1)
Severe	n (%)	11 (27.5)	9 (22.5)	4 (11.8)	5 (14.7)	4 (30.8)	4 (30.8)	19 (21.8)	18 (20.7)
Missing	n (%)	0	0	1 (2.9)	0	0	0	1 (1.1)	0

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 2**

		THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
Individual product preference									
THS 2.2 menthol	n (%)	8 (20.0)	1 (2.5)	3 (8.8)	1 (2.9)	2 (15.4)	0	13 (14.9)	2 (2.3)
mCC	n (%)	11 (27.5)	8 (20.0)	11 (32.4)	10 (29.4)	4 (30.8)	4 (30.8)	26 (29.9)	22 (25.3)
SA	n (%)	0	2 (5.0)	0	0	0	0	0	2 (2.3)
No preference	n (%)	5 (12.5)	5 (12.5)	7 (20.6)	2 (5.9)	2 (15.4)	1 (7.7)	14 (16.1)	8 (9.2)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 2**

		THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
Day 4 SES Questionnaire									
SES educational attainment									
Low	n (%)	2 (5.0)	3 (7.5)	0	0	1 (7.7)	1 (7.7)	3 (3.4)	4 (4.6)
Moderate	n (%)	7 (17.5)	5 (12.5)	9 (26.5)	2 (5.9)	3 (23.1)	2 (15.4)	19 (21.8)	9 (10.3)
High	n (%)	15 (37.5)	8 (20.0)	12 (35.3)	11 (32.4)	4 (30.8)	2 (15.4)	31 (35.6)	21 (24.1)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 2**

		THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
SES annual household income									
Low	n (%)	11 (27.5)	5 (12.5)	11 (32.4)	3 (8.8)	7 (53.8)	3 (23.1)	29 (33.3)	11 (12.6)
Moderate	n (%)	5 (12.5)	4 (10.0)	3 (8.8)	4 (11.8)	1 (7.7)	0	9 (10.3)	8 (9.2)
High	n (%)	4 (10.0)	3 (7.5)	2 (5.9)	2 (5.9)	0	1 (7.7)	6 (6.9)	6 (6.9)
Missing	n (%)	4 (10.0)	4 (10.0)	5 (14.7)	4 (11.8)	0	1 (7.7)	9 (10.3)	9 (10.3)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
		Male	Female	Male	Female	Male	Female	Male	Female
SES Composite									
Low	n (%)	0	0	0	0	1 (7.7)	0	1 (1.1)	0
Moderate	n (%)	11 (27.5)	5 (12.5)	11 (32.4)	3 (8.8)	6 (46.2)	3 (23.1)	28 (32.2)	11 (12.6)
High	n (%)	9 (22.5)	7 (17.5)	5 (14.7)	6 (17.6)	1 (7.7)	1 (7.7)	15 (17.2)	14 (16.1)
Missing	n (%)	4 (10.0)	4 (10.0)	5 (14.7)	4 (11.8)	0	1 (7.7)	9 (10.3)	9 (10.3)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
		Male	Female	Male	Female	Male	Female	Male	Female
Age (years)	n	23	16	21	14	9	3	53	33
	Mean (SD)	37.0 (11.38)	41.4 (12.86)	32.5 (10.50)	34.6 (10.09)	37.7 (8.68)	52.0 (1.74)	35.3 (10.68)	39.5 (12.09)
	Median	32.0	42.0	30.0	32.0	37.0	51.0	33.0	34.0
	Min, Max	25, 66	24, 64	23, 60	23, 55	26, 50	51, 54	23, 66	23, 64

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 3**

		THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
Race									
White	n (%)	17 (43.6)	12 (30.8)	12 (34.3)	11 (31.4)	3 (25.0)	2 (16.7)	32 (37.2)	25 (29.1)
Black or African American	n (%)	6 (15.4)	3 (7.7)	9 (25.7)	2 (5.7)	6 (50.0)	1 (8.3)	21 (24.4)	6 (7.0)
American Indian or Alaska Native	n (%)	0	0	0	0	0	0	0	0
Asian	n (%)	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	n (%)	0	0	0	0	0	0	0	0
Other	n (%)	0	1 (2.6)	0	1 (2.9)	0	0	0	2 (2.3)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
		Male	Female	Male	Female	Male	Female	Male	Female
Weight (kg)	n	23	16	21	14	9	3	53	33
	Mean (SD)	82.57 (15.710)	77.69 (15.673)	78.23 (13.296)	74.08 (13.018)	73.38 (9.542)	63.00 (14.753)	79.29 (14.060)	74.82 (14.664)
	Median	83.00	81.30	78.50	73.65	72.40	63.30	78.60	74.00
	Min, Max	54.6, 115.3	52.9, 105.9	60.9, 103.2	49.3, 97.3	59.5, 87.7	48.1, 77.6	54.6, 115.3	48.1, 105.9
Height (m)	n	23	16	21	14	9	3	53	33
	Mean (SD)	1.753 (0.0595)	1.624 (0.0741)	1.768 (0.0725)	1.643 (0.0706)	1.756 (0.0425)	1.581 (0.0448)	1.759 (0.0620)	1.628 (0.0710)
	Median	1.769	1.625	1.778	1.622	1.755	1.605	1.769	1.616
	Min, Max	1.65, 1.84	1.49, 1.74	1.61, 1.89	1.53, 1.78	1.69, 1.83	1.53, 1.61	1.61, 1.89	1.49, 1.78

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
		Male	Female	Male	Female	Male	Female	Male	Female
BMI (kg/m ²)	n	23	16	21	14	9	3	53	33
	Mean (SD)	26.74 (4.216)	29.29 (4.701)	24.96 (3.413)	27.34 (3.860)	23.79 (2.752)	25.07 (4.718)	25.53 (3.805)	28.08 (4.431)
	Median	27.20	30.65	24.80	28.00	23.20	24.60	25.30	28.00
	Min, Max	19.1, 34.1	20.6, 34.9	20.0, 31.4	18.6, 32.9	19.4, 27.8	20.6, 30.0	19.1, 34.1	18.6, 34.9
Underweight	n (%)	0	0	0	0	0	0	0	0
Normal weight	n (%)	7 (17.9)	3 (7.7)	11 (31.4)	4 (11.4)	6 (50.0)	2 (16.7)	24 (27.9)	9 (10.5)
Overweight	n (%)	11 (28.2)	4 (10.3)	7 (20.0)	7 (20.0)	3 (25.0)	0	21 (24.4)	11 (12.8)
Obese	n (%)	5 (12.8)	9 (23.1)	3 (8.6)	3 (8.6)	0	1 (8.3)	8 (9.3)	13 (15.1)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
		Male	Female	Male	Female	Male	Female	Male	Female
Waist circumference (cm)	n	23	16	21	14	9	3	53	33
	Mean (SD)	95.0 (11.13)	101.9 (19.58)	90.6 (9.04)	104.9 (27.00)	85.6 (10.97)	87.3 (12.67)	91.6 (10.68)	101.8 (22.58)
	Median	98.0	97.5	87.0	94.5	81.0	92.0	91.0	97.0
	Min, Max	73, 113	76, 149	80, 110	77, 169	73, 106	73, 97	73, 113	73, 169
Cigarette consumption									
10-19 cig/day	n (%)	12 (30.8)	4 (10.3)	14 (40.0)	6 (17.1)	7 (58.3)	1 (8.3)	33 (38.4)	11 (12.8)
>19 cig/day	n (%)	11 (28.2)	12 (30.8)	7 (20.0)	8 (22.9)	2 (16.7)	2 (16.7)	20 (23.3)	22 (25.6)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
		Male	Female	Male	Female	Male	Female	Male	Female
FTND score	n	23	16	20	14	9	3	52	33
	Mean (SD)	5.9 (1.99)	6.0 (2.37)	5.3 (1.81)	5.9 (1.57)	5.2 (2.54)	7.3 (1.16)	5.5 (2.01)	6.1 (1.97)
	Median	6.0	6.0	5.0	6.0	6.0	8.0	6.0	6.0
	Min, Max	1, 9	1, 10	1, 9	3, 8	2, 8	6, 8	1, 9	1, 10
FTND score									
Mild	n (%)	2 (5.1)	2 (5.1)	3 (8.6)	1 (2.9)	3 (25.0)	0	8 (9.3)	3 (3.5)
Moderate	n (%)	10 (25.6)	7 (17.9)	13 (37.1)	8 (22.9)	3 (25.0)	1 (8.3)	26 (30.2)	16 (18.6)
Severe	n (%)	11 (28.2)	7 (17.9)	4 (11.4)	5 (14.3)	3 (25.0)	2 (16.7)	18 (20.9)	14 (16.3)
Missing	n (%)	0	0	1 (2.9)	0	0	0	1 (1.2)	0

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 3**

		THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
Individual product preference									
THS 2.2 menthol	n (%)	5 (12.8)	1 (2.6)	3 (8.6)	1 (2.9)	2 (16.7)	0	10 (11.6)	2 (2.3)
mCC	n (%)	11 (28.2)	7 (17.9)	11 (31.4)	11 (31.4)	5 (41.7)	3 (25.0)	27 (31.4)	21 (24.4)
SA	n (%)	0	2 (5.1)	0	0	0	0	0	2 (2.3)
No preference	n (%)	7 (17.9)	6 (15.4)	7 (20.0)	2 (5.7)	2 (16.7)	0	16 (18.6)	8 (9.3)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 3**

		THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
Day 4 SES Questionnaire									
SES educational attainment									
Low	n (%)	2 (5.1)	3 (7.7)	0	0	1 (8.3)	0	3 (3.5)	3 (3.5)
Moderate	n (%)	7 (17.9)	3 (7.7)	9 (25.7)	3 (8.6)	3 (25.0)	2 (16.7)	19 (22.1)	8 (9.3)
High	n (%)	14 (35.9)	10 (25.6)	12 (34.3)	11 (31.4)	5 (41.7)	1 (8.3)	31 (36.0)	22 (25.6)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 3**

		THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
SES annual household income									
Low	n (%)	9 (23.1)	4 (10.3)	11 (31.4)	4 (11.4)	7 (58.3)	2 (16.7)	27 (31.4)	10 (11.6)
Moderate	n (%)	4 (10.3)	4 (10.3)	3 (8.6)	4 (11.4)	0	0	7 (8.1)	8 (9.3)
High	n (%)	5 (12.8)	3 (7.7)	2 (5.7)	2 (5.7)	2 (16.7)	1 (8.3)	9 (10.5)	6 (7.0)
Missing	n (%)	5 (12.8)	5 (12.8)	5 (14.3)	4 (11.4)	0	0	10 (11.6)	9 (10.5)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 3**

		THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
SES Composite									
Low	n (%)	0	0	0	0	1 (8.3)	0	1 (1.2)	0
Moderate	n (%)	9 (23.1)	4 (10.3)	11 (31.4)	4 (11.4)	6 (50.0)	2 (16.7)	26 (30.2)	10 (11.6)
High	n (%)	9 (23.1)	7 (17.9)	5 (14.3)	6 (17.1)	2 (16.7)	1 (8.3)	16 (18.6)	14 (16.3)
Missing	n (%)	5 (12.8)	5 (12.8)	5 (14.3)	4 (11.4)	0	0	10 (11.6)	9 (10.5)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
		Male	Female	Male	Female	Male	Female	Male	Female
Age (years)	n	28	19	19	13	7	2	54	34
	Mean (SD)	36.1 (11.54)	39.7 (12.44)	33.4 (10.65)	34.8 (10.48)	37.3 (9.71)	52.5 (2.13)	35.3 (10.92)	38.6 (11.95)
	Median	32.0	38.0	33.0	32.0	37.0	52.5	32.0	34.0
	Min, Max	25, 66	24, 64	23, 60	23, 55	26, 50	51, 54	23, 66	23, 64

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 4**

		THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
Race									
White	n (%)	20 (42.6)	14 (29.8)	10 (31.3)	10 (31.3)	2 (22.2)	2 (22.2)	32 (36.4)	26 (29.5)
Black or African American	n (%)	6 (12.8)	4 (8.5)	9 (28.1)	2 (6.3)	5 (55.6)	0	20 (22.7)	6 (6.8)
American Indian or Alaska Native	n (%)	0	0	0	0	0	0	0	0
Asian	n (%)	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	n (%)	0	0	0	0	0	0	0	0
Other	n (%)	2 (4.3)	1 (2.1)	0	1 (3.1)	0	0	2 (2.3)	2 (2.3)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
		Male	Female	Male	Female	Male	Female	Male	Female
Weight (kg)	n	28	19	19	13	7	2	54	34
	Mean (SD)	80.62 (15.199)	76.47 (14.664)	79.94 (12.804)	74.28 (13.528)	71.47 (9.101)	55.70 (10.749)	79.19 (13.852)	74.41 (14.526)
	Median	80.65	74.60	80.30	73.70	71.00	55.70	78.55	73.85
	Min, Max	54.6, 115.3	52.9, 105.9	64.7, 103.2	49.3, 97.3	59.5, 85.8	48.1, 63.3	54.6, 115.3	48.1, 105.9
Height (m)	n	28	19	19	13	7	2	54	34
	Mean (SD)	1.755 (0.0573)	1.623 (0.0699)	1.775 (0.0662)	1.647 (0.0722)	1.755 (0.0478)	1.567 (0.0538)	1.762 (0.0593)	1.629 (0.0709)
	Median	1.765	1.620	1.780	1.627	1.755	1.567	1.769	1.618
	Min, Max	1.65, 1.84	1.49, 1.74	1.66, 1.89	1.53, 1.78	1.69, 1.83	1.53, 1.61	1.65, 1.89	1.49, 1.78

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
		Male	Female	Male	Female	Male	Female	Male	Female
BMI (kg/m ²)	n	28	19	19	13	7	2	54	34
	Mean (SD)	26.10 (4.286)	28.88 (4.401)	25.29 (3.368)	27.29 (4.013)	23.20 (2.648)	22.60 (2.829)	25.44 (3.860)	27.91 (4.367)
	Median	26.90	27.10	25.10	28.00	23.10	22.60	25.60	26.95
	Min, Max	19.1, 34.1	20.6, 34.9	20.2, 31.4	18.6, 32.9	19.4, 27.1	20.6, 24.6	19.1, 34.1	18.6, 34.9
Underweight	n (%)	0	0	0	0	0	0	0	0
Normal weight	n (%)	10 (21.3)	3 (6.4)	9 (28.1)	4 (12.5)	5 (55.6)	2 (22.2)	24 (27.3)	9 (10.2)
Overweight	n (%)	13 (27.7)	7 (14.9)	7 (21.9)	6 (18.8)	2 (22.2)	0	22 (25.0)	13 (14.8)
Obese	n (%)	5 (10.6)	9 (19.1)	3 (9.4)	3 (9.4)	0	0	8 (9.1)	12 (13.6)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
		Male	Female	Male	Female	Male	Female	Male	Female
Waist circumference (cm)	n	28	19	19	13	7	2	54	34
	Mean (SD)	93.1 (11.19)	99.8 (18.71)	91.2 (9.18)	105.9 (27.84)	81.7 (8.16)	82.5 (13.44)	90.9 (10.66)	101.1 (22.57)
	Median	93.0	97.0	87.0	97.0	81.0	82.5	88.0	95.5
	Min, Max	73, 113	76, 149	81, 110	77, 169	73, 98	73, 92	73, 113	73, 169
Cigarette consumption									
10-19 cig/day	n (%)	17 (36.2)	4 (8.5)	13 (40.6)	6 (18.8)	5 (55.6)	1 (11.1)	35 (39.8)	11 (12.5)
>19 cig/day	n (%)	11 (23.4)	15 (31.9)	6 (18.8)	7 (21.9)	2 (22.2)	1 (11.1)	19 (21.6)	23 (26.1)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
		Male	Female	Male	Female	Male	Female	Male	Female
FTND score	n	28	19	19	13	7	2	54	34
	Mean (SD)	5.6 (2.09)	6.2 (2.42)	5.3 (1.86)	6.1 (1.39)	5.6 (2.58)	7.0 (1.42)	5.5 (2.04)	6.2 (2.00)
	Median	6.0	6.0	5.0	6.0	6.0	7.0	6.0	6.0
	Min, Max	1, 9	1, 10	1, 9	4, 8	2, 8	6, 8	1, 9	1, 10
FTND score									
Mild	n (%)	5 (10.6)	2 (4.3)	3 (9.4)	0	2 (22.2)	0	10 (11.4)	2 (2.3)
Moderate	n (%)	11 (23.4)	8 (17.0)	12 (37.5)	8 (25.0)	2 (22.2)	1 (11.1)	25 (28.4)	17 (19.3)
Severe	n (%)	12 (25.5)	9 (19.1)	4 (12.5)	5 (15.6)	3 (33.3)	1 (11.1)	19 (21.6)	15 (17.0)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 4**

		THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
Individual product preference									
THS 2.2 menthol	n (%)	6 (12.8)	1 (2.1)	2 (6.3)	1 (3.1)	2 (22.2)	0	10 (11.4)	2 (2.3)
mCC	n (%)	14 (29.8)	9 (19.1)	11 (34.4)	10 (31.3)	3 (33.3)	2 (22.2)	28 (31.8)	21 (23.9)
SA	n (%)	0	2 (4.3)	0	0	0	0	0	2 (2.3)
No preference	n (%)	8 (17.0)	7 (14.9)	6 (18.8)	2 (6.3)	2 (22.2)	0	16 (18.2)	9 (10.2)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 4**

		THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
Day 4 SES Questionnaire									
SES educational attainment									
Low	n (%)	2 (4.3)	3 (6.4)	0	0	1 (11.1)	0	3 (3.4)	3 (3.4)
Moderate	n (%)	10 (21.3)	5 (10.6)	7 (21.9)	2 (6.3)	3 (33.3)	1 (11.1)	20 (22.7)	8 (9.1)
High	n (%)	16 (34.0)	11 (23.4)	12 (37.5)	11 (34.4)	3 (33.3)	1 (11.1)	31 (35.2)	23 (26.1)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 4**

		THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
SES annual household income									
Low	n (%)	14 (29.8)	6 (12.8)	10 (31.3)	3 (9.4)	6 (66.7)	1 (11.1)	30 (34.1)	10 (11.4)
Moderate	n (%)	4 (8.5)	5 (10.6)	3 (9.4)	4 (12.5)	0	0	7 (8.0)	9 (10.2)
High	n (%)	5 (10.6)	3 (6.4)	2 (6.3)	2 (6.3)	1 (11.1)	1 (11.1)	8 (9.1)	6 (6.8)
Missing	n (%)	5 (10.6)	5 (10.6)	4 (12.5)	4 (12.5)	0	0	9 (10.2)	9 (10.2)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.1 Summary of Demographics and Other Baseline Characteristics by Sex - PP Set****Product Use Time Period: Period 4**

		THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
Variable	Statistic	Male	Female	Male	Female	Male	Female	Male	Female
SES Composite									
Low	n (%)	0	0	0	0	1 (11.1)	0	1 (1.1)	0
Moderate	n (%)	14 (29.8)	6 (12.8)	10 (31.3)	3 (9.4)	5 (55.6)	1 (11.1)	29 (33.0)	10 (11.4)
High	n (%)	9 (19.1)	8 (17.0)	5 (15.6)	6 (18.8)	1 (11.1)	1 (11.1)	15 (17.0)	15 (17.0)
Missing	n (%)	5 (10.6)	5 (10.6)	4 (12.5)	4 (12.5)	0	0	9 (10.2)	9 (10.2)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

		THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Sex									
Male	n (%)	31 (41.3)	15 (20.0)	14 (40.0)	6 (17.1)	10 (41.7)	5 (20.8)	55 (41.0)	26 (19.4)
Female	n (%)	12 (16.0)	17 (22.7)	6 (17.1)	9 (25.7)	3 (12.5)	6 (25.0)	21 (15.7)	32 (23.9)
Age (years)									
	n	43	32	20	15	13	11	76	58
	Mean (SD)	38.6 (11.10)	39.6 (12.77)	32.6 (9.03)	36.1 (12.17)	39.2 (10.30)	42.1 (11.64)	37.1 (10.69)	39.2 (12.37)
	Median	37.0	35.5	32.0	32.0	37.0	47.0	34.0	35.5
	Min, Max	22, 60	24, 66	23, 58	23, 60	26, 57	22, 54	22, 60	22, 66

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

		THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Race									
White	n (%)	23 (30.7)	23 (30.7)	13 (37.1)	11 (31.4)	7 (29.2)	6 (25.0)	43 (32.1)	40 (29.9)
Black or African American	n (%)	15 (20.0)	7 (9.3)	6 (17.1)	4 (11.4)	6 (25.0)	5 (20.8)	27 (20.1)	16 (11.9)
American Indian or Alaska Native	n (%)	0	0	0	0	0	0	0	0
Asian	n (%)	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	n (%)	0	0	0	0	0	0	0	0
Other	n (%)	5 (6.7)	2 (2.7)	1 (2.9)	0	0	0	6 (4.5)	2 (1.5)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Weight (kg)	n	43	32	20	15	13	11	76	58
	Mean (SD)	78.61 (12.121)	80.51 (16.039)	77.12 (11.145)	75.87 (15.820)	76.11 (14.263)	74.08 (6.465)	77.79 (12.136)	78.09 (14.711)
	Median	77.50	84.05	76.95	71.50	73.50	74.70	77.15	77.25
	Min, Max	57.2, 108.8	52.9, 115.3	60.9, 101.0	49.3, 103.2	48.1, 97.1	63.3, 83.1	48.1, 108.8	49.3, 115.3
Height (m)	n	43	32	20	15	13	11	76	58
	Mean (SD)	1.719 (0.0729)	1.694 (0.1019)	1.730 (0.0864)	1.692 (0.1147)	1.719 (0.0919)	1.693 (0.0859)	1.722 (0.0790)	1.693 (0.1008)
	Median	1.730	1.686	1.720	1.716	1.755	1.675	1.731	1.689
	Min, Max	1.53, 1.83	1.49, 1.84	1.60, 1.89	1.51, 1.85	1.53, 1.83	1.60, 1.85	1.53, 1.89	1.49, 1.85

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
BMI (kg/m ²)	n	43	32	20	15	13	11	76	58
	Mean (SD)	26.66 (4.124)	27.92 (4.107)	25.75 (3.100)	26.48 (4.668)	25.61 (3.352)	26.00 (3.250)	26.24 (3.741)	27.18 (4.133)
	Median	26.40	27.30	25.40	26.50	24.60	24.60	25.40	27.20
	Min, Max	20.3, 34.4	19.1, 34.9	22.0, 31.6	18.6, 32.9	20.6, 31.5	21.8, 32.0	20.3, 34.4	18.6, 34.9
Underweight	n (%)	0	0	0	0	0	0	0	0
Normal weight	n (%)	19 (25.3)	5 (6.7)	9 (25.7)	6 (17.1)	7 (29.2)	6 (25.0)	35 (26.1)	17 (12.7)
Overweight	n (%)	13 (17.3)	17 (22.7)	9 (25.7)	4 (11.4)	5 (20.8)	3 (12.5)	27 (20.1)	24 (17.9)
Obese	n (%)	11 (14.7)	10 (13.3)	2 (5.7)	5 (14.3)	1 (4.2)	2 (8.3)	14 (10.4)	17 (12.7)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Waist circumference (cm)	n	43	32	20	15	13	11	76	58
	Mean (SD)	92.6 (17.95)	100.9 (18.76)	91.8 (9.87)	103.2 (26.28)	90.9 (12.02)	93.8 (7.61)	92.1 (15.12)	100.1 (19.53)
	Median	92.0	99.5	91.0	97.0	87.0	92.0	91.0	97.5
	Min, Max	28, 161	73, 167	77, 115	80, 169	73, 109	78, 104	28, 161	73, 169

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Variable	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
FTND score	n	43	32	20	14	13	11	76	57
	Mean (SD)	5.0 (2.20)	6.6 (2.05)	5.1 (1.64)	6.2 (1.63)	4.5 (2.15)	6.7 (1.01)	4.9 (2.04)	6.5 (1.78)
	Median	5.0	7.0	5.0	6.0	5.0	7.0	5.0	7.0
	Min, Max	0, 8	1, 10	1, 8	3, 9	2, 8	5, 8	0, 8	1, 10
FTND score									
Mild	n (%)	11 (14.7)	2 (2.7)	3 (8.6)	1 (2.9)	5 (20.8)	0	19 (14.2)	3 (2.2)
Moderate	n (%)	18 (24.0)	13 (17.3)	14 (40.0)	7 (20.0)	6 (25.0)	5 (20.8)	38 (28.4)	25 (18.7)
Severe	n (%)	14 (18.7)	17 (22.7)	3 (8.6)	6 (17.1)	2 (8.3)	6 (25.0)	19 (14.2)	29 (21.6)
Missing	n (%)	0	0	0	1 (2.9)	0	0	0	1 (0.7)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

		THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Individual product preference									
THS 2.2 menthol	n (%)	6 (8.0)	4 (5.3)	2 (5.7)	2 (5.7)	6 (25.0)	3 (12.5)	14 (10.4)	9 (6.7)
mCC	n (%)	22 (29.3)	15 (20.0)	11 (31.4)	11 (31.4)	6 (25.0)	4 (16.7)	39 (29.1)	30 (22.4)
SA	n (%)	1 (1.3)	1 (1.3)	0	0	0	0	1 (0.7)	1 (0.7)
No preference	n (%)	14 (18.7)	12 (16.0)	7 (20.0)	2 (5.7)	1 (4.2)	4 (16.7)	22 (16.4)	18 (13.4)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

		THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Day 4 SES Questionnaire									
SES educational attainment									
Low	n (%)	2 (2.7)	4 (5.3)	0	0	1 (4.2)	1 (4.2)	3 (2.2)	5 (3.7)
Moderate	n (%)	14 (18.7)	10 (13.3)	8 (22.9)	4 (11.4)	2 (8.3)	5 (20.8)	24 (17.9)	19 (14.2)
High	n (%)	27 (36.0)	18 (24.0)	12 (34.3)	10 (28.6)	10 (41.7)	5 (20.8)	49 (36.6)	33 (24.6)
Missing	n (%)	0	0	0	1 (2.9)	0	0	0	1 (0.7)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

		THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
SES annual household income									
Low	n (%)	16 (21.3)	10 (13.3)	7 (20.0)	7 (20.0)	6 (25.0)	3 (12.5)	29 (21.6)	20 (14.9)
Moderate	n (%)	13 (17.3)	7 (9.3)	6 (17.1)	1 (2.9)	2 (8.3)	4 (16.7)	21 (15.7)	12 (9.0)
High	n (%)	6 (8.0)	7 (9.3)	3 (8.6)	1 (2.9)	5 (20.8)	1 (4.2)	14 (10.4)	9 (6.7)
Missing	n (%)	8 (10.7)	8 (10.7)	4 (11.4)	6 (17.1)	0	3 (12.5)	12 (9.0)	17 (12.7)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

		THSm2.2 (N=75)		mCC (N=35)		SA (N=24)		Overall PP Set (N=134)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
SES Composite									
Low	n (%)	0	0	0	0	0	0	0	0
Moderate	n (%)	17 (22.7)	10 (13.3)	7 (20.0)	7 (20.0)	7 (29.2)	3 (12.5)	31 (23.1)	20 (14.9)
High	n (%)	18 (24.0)	14 (18.7)	9 (25.7)	2 (5.7)	6 (25.0)	5 (20.8)	33 (24.6)	21 (15.7)
Missing	n (%)	8 (10.7)	8 (10.7)	4 (11.4)	6 (17.1)	0	3 (12.5)	12 (9.0)	17 (12.7)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 2**

		THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Sex									
Male	n (%)	14 (35.0)	10 (25.0)	14 (41.2)	7 (20.6)	6 (46.2)	2 (15.4)	34 (39.1)	19 (21.8)
Female	n (%)	4 (10.0)	12 (30.0)	5 (14.7)	8 (23.5)	1 (7.7)	4 (30.8)	10 (11.5)	24 (27.6)
Age (years)									
	n	18	22	19	15	7	6	44	43
	Mean (SD)	37.4 (10.47)	40.1 (13.09)	32.6 (9.28)	34.4 (11.90)	38.1 (10.16)	42.5 (12.54)	35.4 (10.01)	38.4 (12.70)
	Median	32.5	37.0	32.0	29.0	37.0	44.5	32.5	35.0
	Min, Max	25, 56	24, 66	23, 58	23, 60	26, 51	22, 54	23, 58	22, 66

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 2**

		THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Race									
White	n (%)	12 (30.0)	18 (45.0)	12 (35.3)	10 (29.4)	2 (15.4)	3 (23.1)	26 (29.9)	31 (35.6)
Black or African American	n (%)	6 (15.0)	4 (10.0)	6 (17.6)	5 (14.7)	5 (38.5)	3 (23.1)	17 (19.5)	12 (13.8)
American Indian or Alaska Native	n (%)	0	0	0	0	0	0	0	0
Asian	n (%)	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	n (%)	0	0	0	0	0	0	0	0
Other	n (%)	0	0	1 (2.9)	0	0	0	1 (1.1)	0

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Weight (kg)	n	18	22	19	15	7	6	44	43
	Mean (SD)	80.77 (12.900)	77.23 (15.949)	77.95 (10.793)	75.84 (15.833)	68.49 (12.994)	72.95 (6.171)	77.60 (12.485)	76.15 (14.744)
	Median	79.35	78.80	78.50	71.50	71.00	74.35	78.35	74.60
	Min, Max	59.5, 104.7	52.9, 108.7	60.9, 101.0	49.3, 103.2	48.1, 87.7	63.3, 79.7	48.1, 104.7	49.3, 108.7
Height (m)	n	18	22	19	15	7	6	44	43
	Mean (SD)	1.725 (0.0676)	1.678 (0.1041)	1.736 (0.0839)	1.702 (0.1038)	1.729 (0.0984)	1.662 (0.0557)	1.730 (0.0783)	1.684 (0.0979)
	Median	1.722	1.679	1.720	1.716	1.755	1.654	1.729	1.682
	Min, Max	1.59, 1.83	1.49, 1.84	1.60, 1.89	1.53, 1.85	1.53, 1.83	1.61, 1.74	1.53, 1.89	1.49, 1.85

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
BMI (kg/m ²)	n	18	22	19	15	7	6	44	43
	Mean (SD)	27.22 (4.454)	27.30 (4.373)	25.86 (3.143)	26.13 (4.556)	22.76 (2.794)	26.48 (2.643)	25.92 (3.925)	26.78 (4.197)
	Median	27.10	27.15	25.50	26.10	23.10	26.60	25.85	26.80
	Min, Max	20.3, 34.4	19.1, 34.3	22.0, 31.6	18.6, 32.9	19.4, 27.8	22.7, 30.0	19.4, 34.4	18.6, 34.3
Underweight	n (%)	0	0	0	0	0	0	0	0
Normal weight	n (%)	6 (15.0)	5 (12.5)	8 (23.5)	6 (17.6)	6 (46.2)	2 (15.4)	20 (23.0)	13 (14.9)
Overweight	n (%)	7 (17.5)	10 (25.0)	9 (26.5)	5 (14.7)	1 (7.7)	3 (23.1)	17 (19.5)	18 (20.7)
Obese	n (%)	5 (12.5)	7 (17.5)	2 (5.9)	4 (11.8)	0	1 (7.7)	7 (8.0)	12 (13.8)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Waist circumference (cm)	n	18	22	19	15	7	6	44	43
	Mean (SD)	94.3 (14.14)	97.2 (16.23)	92.6 (9.48)	102.4 (26.75)	82.3 (11.49)	92.7 (9.69)	91.6 (12.35)	98.4 (19.82)
	Median	92.0	97.5	91.0	97.0	81.0	94.5	91.0	97.0
	Min, Max	73, 127	73, 149	81, 115	80, 169	73, 106	78, 103	73, 127	73, 169

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 2**

Variable	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
FTND score	n	18	22	19	14	7	6	44	42
	Mean (SD)	4.9 (2.10)	7.0 (1.64)	5.1 (1.67)	6.2 (1.63)	6.0 (1.92)	7.5 (0.84)	5.2 (1.89)	6.8 (1.59)
	Median	5.0	7.0	5.0	6.0	6.0	8.0	6.0	7.0
	Min, Max	1, 8	4, 10	1, 8	3, 9	3, 8	6, 8	1, 8	3, 10
FTND score									
Mild	n (%)	4 (10.0)	0	3 (8.8)	1 (2.9)	1 (7.7)	0	8 (9.2)	1 (1.1)
Moderate	n (%)	8 (20.0)	8 (20.0)	13 (38.2)	7 (20.6)	3 (23.1)	1 (7.7)	24 (27.6)	16 (18.4)
Severe	n (%)	6 (15.0)	14 (35.0)	3 (8.8)	6 (17.6)	3 (23.1)	5 (38.5)	12 (13.8)	25 (28.7)
Missing	n (%)	0	0	0	1 (2.9)	0	0	0	1 (1.1)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 2**

		THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Individual product preference									
THS 2.2 menthol	n (%)	5 (12.5)	4 (10.0)	2 (5.9)	2 (5.9)	2 (15.4)	0	9 (10.3)	6 (6.9)
mCC	n (%)	9 (22.5)	10 (25.0)	10 (29.4)	11 (32.4)	3 (23.1)	5 (38.5)	22 (25.3)	26 (29.9)
SA	n (%)	1 (2.5)	1 (2.5)	0	0	0	0	1 (1.1)	1 (1.1)
No preference	n (%)	3 (7.5)	7 (17.5)	7 (20.6)	2 (5.9)	2 (15.4)	1 (7.7)	12 (13.8)	10 (11.5)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 2**

		THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Day 4 SES Questionnaire									
SES educational attainment									
Low	n (%)	1 (2.5)	4 (10.0)	0	0	1 (7.7)	1 (7.7)	2 (2.3)	5 (5.7)
Moderate	n (%)	5 (12.5)	7 (17.5)	7 (20.6)	4 (11.8)	2 (15.4)	3 (23.1)	14 (16.1)	14 (16.1)
High	n (%)	12 (30.0)	11 (27.5)	12 (35.3)	11 (32.4)	4 (30.8)	2 (15.4)	28 (32.2)	24 (27.6)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 2**

		THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
SES annual household income									
Low	n (%)	8 (20.0)	8 (20.0)	6 (17.6)	8 (23.5)	6 (46.2)	4 (30.8)	20 (23.0)	20 (23.0)
Moderate	n (%)	5 (12.5)	4 (10.0)	6 (17.6)	1 (2.9)	1 (7.7)	0	12 (13.8)	5 (5.7)
High	n (%)	3 (7.5)	4 (10.0)	3 (8.8)	1 (2.9)	0	1 (7.7)	6 (6.9)	6 (6.9)
Missing	n (%)	2 (5.0)	6 (15.0)	4 (11.8)	5 (14.7)	0	1 (7.7)	6 (6.9)	12 (13.8)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 2**

		THSm2.2 (N=40)		mCC (N=34)		SA (N=13)		Overall PP Set (N=87)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
SES Composite									
Low	n (%)	0	0	0	0	1 (7.7)	0	1 (1.1)	0
Moderate	n (%)	8 (20.0)	8 (20.0)	6 (17.6)	8 (23.5)	5 (38.5)	4 (30.8)	19 (21.8)	20 (23.0)
High	n (%)	8 (20.0)	8 (20.0)	9 (26.5)	2 (5.9)	1 (7.7)	1 (7.7)	18 (20.7)	11 (12.6)
Missing	n (%)	2 (5.0)	6 (15.0)	4 (11.8)	5 (14.7)	0	1 (7.7)	6 (6.9)	12 (13.8)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 3**

		THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Sex									
Male	n (%)	12 (30.8)	11 (28.2)	14 (40.0)	7 (20.0)	7 (58.3)	2 (16.7)	33 (38.4)	20 (23.3)
Female	n (%)	4 (10.3)	12 (30.8)	6 (17.1)	8 (22.9)	1 (8.3)	2 (16.7)	11 (12.8)	22 (25.6)
Age (years)									
	n	16	23	20	15	8	4	44	42
	Mean (SD)	38.4 (10.13)	39.0 (13.43)	32.6 (9.03)	34.4 (11.90)	39.4 (10.40)	45.0 (8.76)	35.9 (9.96)	38.0 (12.69)
	Median	33.5	36.0	32.0	29.0	39.0	44.5	33.0	33.5
	Min, Max	26, 56	24, 66	23, 58	23, 60	26, 51	37, 54	23, 58	23, 66

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 3**

		THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Race									
White	n (%)	11 (28.2)	18 (46.2)	13 (37.1)	10 (28.6)	4 (33.3)	1 (8.3)	28 (32.6)	29 (33.7)
Black or African American	n (%)	5 (12.8)	4 (10.3)	6 (17.1)	5 (14.3)	4 (33.3)	3 (25.0)	15 (17.4)	12 (14.0)
American Indian or Alaska Native	n (%)	0	0	0	0	0	0	0	0
Asian	n (%)	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	n (%)	0	0	0	0	0	0	0	0
Other	n (%)	0	1 (2.6)	1 (2.9)	0	0	0	1 (1.2)	1 (1.2)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Weight (kg)	n	16	23	20	15	8	4	44	42
	Mean (SD)	79.99 (11.801)	80.97 (18.142)	77.12 (11.145)	75.84 (15.833)	70.51 (13.470)	71.33 (6.688)	76.96 (12.007)	78.22 (16.626)
	Median	79.35	84.30	76.95	71.50	71.70	72.20	77.90	77.25
	Min, Max	59.5, 101.9	52.9, 115.3	60.9, 101.0	49.3, 103.2	48.1, 87.7	63.3, 77.6	48.1, 101.9	49.3, 115.3
Height (m)	n	16	23	20	15	8	4	44	42
	Mean (SD)	1.716 (0.0640)	1.689 (0.1064)	1.730 (0.0864)	1.702 (0.1038)	1.735 (0.0928)	1.666 (0.0692)	1.726 (0.0787)	1.692 (0.1010)
	Median	1.718	1.690	1.720	1.716	1.766	1.661	1.729	1.693
	Min, Max	1.59, 1.82	1.49, 1.84	1.60, 1.89	1.53, 1.85	1.53, 1.83	1.61, 1.74	1.53, 1.89	1.49, 1.85

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
BMI (kg/m ²)	n	16	23	20	15	8	4	44	42
	Mean (SD)	27.22 (4.179)	28.19 (4.830)	25.75 (3.100)	26.13 (4.556)	23.26 (2.998)	25.80 (3.094)	25.83 (3.708)	27.23 (4.632)
	Median	27.10	28.90	25.40	26.10	23.15	25.25	25.40	27.15
	Min, Max	20.3, 34.4	19.1, 34.9	22.0, 31.6	18.6, 32.9	19.4, 27.8	22.7, 30.0	19.4, 34.4	18.6, 34.9
Underweight	n (%)	0	0	0	0	0	0	0	0
Normal weight	n (%)	5 (12.8)	5 (12.8)	9 (25.7)	6 (17.1)	6 (50.0)	2 (16.7)	20 (23.3)	13 (15.1)
Overweight	n (%)	7 (17.9)	8 (20.5)	9 (25.7)	5 (14.3)	2 (16.7)	1 (8.3)	18 (20.9)	14 (16.3)
Obese	n (%)	4 (10.3)	10 (25.6)	2 (5.7)	4 (11.4)	0	1 (8.3)	6 (7.0)	15 (17.4)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Waist circumference (cm)	n	16	23	20	15	8	4	44	42
	Mean (SD)	95.1 (13.74)	99.7 (16.38)	91.8 (9.87)	102.4 (26.75)	85.0 (12.31)	88.0 (8.29)	91.8 (12.10)	99.5 (20.23)
	Median	93.0	99.0	91.0	97.0	81.0	88.5	91.0	97.5
	Min, Max	76, 127	73, 149	77, 115	80, 169	73, 106	78, 97	73, 127	73, 169

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 3**

Variable	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
FTND score	n	16	23	20	14	8	4	44	41
	Mean (SD)	5.1 (2.24)	6.5 (1.86)	5.1 (1.64)	6.2 (1.63)	4.9 (2.48)	7.5 (1.00)	5.0 (1.99)	6.5 (1.72)
	Median	5.0	7.0	5.0	6.0	5.0	8.0	5.0	7.0
	Min, Max	1, 8	1, 10	1, 8	3, 9	2, 8	6, 8	1, 8	1, 10
FTND score									
Mild	n (%)	3 (7.7)	1 (2.6)	3 (8.6)	1 (2.9)	3 (25.0)	0	9 (10.5)	2 (2.3)
Moderate	n (%)	7 (17.9)	10 (25.6)	14 (40.0)	7 (20.0)	3 (25.0)	1 (8.3)	24 (27.9)	18 (20.9)
Severe	n (%)	6 (15.4)	12 (30.8)	3 (8.6)	6 (17.1)	2 (16.7)	3 (25.0)	11 (12.8)	21 (24.4)
Missing	n (%)	0	0	0	1 (2.9)	0	0	0	1 (1.2)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 3**

		THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Individual product preference									
THS 2.2 menthol	n (%)	2 (5.1)	4 (10.3)	2 (5.7)	2 (5.7)	2 (16.7)	0	6 (7.0)	6 (7.0)
mCC	n (%)	8 (20.5)	10 (25.6)	11 (31.4)	11 (31.4)	4 (33.3)	4 (33.3)	23 (26.7)	25 (29.1)
SA	n (%)	1 (2.6)	1 (2.6)	0	0	0	0	1 (1.2)	1 (1.2)
No preference	n (%)	5 (12.8)	8 (20.5)	7 (20.0)	2 (5.7)	2 (16.7)	0	14 (16.3)	10 (11.6)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 3**

		THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Day 4 SES Questionnaire									
SES educational attainment									
Low	n (%)	1 (2.6)	4 (10.3)	0	0	1 (8.3)	0	2 (2.3)	4 (4.7)
Moderate	n (%)	5 (12.8)	5 (12.8)	8 (22.9)	4 (11.4)	2 (16.7)	3 (25.0)	15 (17.4)	12 (14.0)
High	n (%)	10 (25.6)	14 (35.9)	12 (34.3)	11 (31.4)	5 (41.7)	1 (8.3)	27 (31.4)	26 (30.2)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 3**

		THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
SES annual household income									
Low	n (%)	6 (15.4)	7 (17.9)	7 (20.0)	8 (22.9)	6 (50.0)	3 (25.0)	19 (22.1)	18 (20.9)
Moderate	n (%)	4 (10.3)	4 (10.3)	6 (17.1)	1 (2.9)	0	0	10 (11.6)	5 (5.8)
High	n (%)	4 (10.3)	4 (10.3)	3 (8.6)	1 (2.9)	2 (16.7)	1 (8.3)	9 (10.5)	6 (7.0)
Missing	n (%)	2 (5.1)	8 (20.5)	4 (11.4)	5 (14.3)	0	0	6 (7.0)	13 (15.1)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 3**

		THSm2.2 (N=39)		mCC (N=35)		SA (N=12)		Overall PP Set (N=86)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
SES Composite									
Low	n (%)	0	0	0	0	1 (8.3)	0	1 (1.2)	0
Moderate	n (%)	6 (15.4)	7 (17.9)	7 (20.0)	8 (22.9)	5 (41.7)	3 (25.0)	18 (20.9)	18 (20.9)
High	n (%)	8 (20.5)	8 (20.5)	9 (25.7)	2 (5.7)	2 (16.7)	1 (8.3)	19 (22.1)	11 (12.8)
Missing	n (%)	2 (5.1)	8 (20.5)	4 (11.4)	5 (14.3)	0	0	6 (7.0)	13 (15.1)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 4**

		THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Sex									
Male	n (%)	17 (36.2)	11 (23.4)	13 (40.6)	6 (18.8)	5 (55.6)	2 (22.2)	35 (39.8)	19 (21.6)
Female	n (%)	4 (8.5)	15 (31.9)	6 (18.8)	7 (21.9)	1 (11.1)	1 (11.1)	11 (12.5)	23 (26.1)
Age (years)									
	n	21	26	19	13	6	3	46	42
	Mean (SD)	36.9 (10.82)	38.1 (12.92)	33.0 (9.05)	35.4 (12.44)	39.5 (12.03)	43.0 (9.54)	35.6 (10.32)	37.6 (12.47)
	Median	32.0	34.0	32.0	29.0	41.0	38.0	32.0	33.5
	Min, Max	25, 56	24, 66	23, 58	23, 60	26, 51	37, 54	23, 58	23, 66

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 4**

		THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Race									
White	n (%)	14 (29.8)	20 (42.6)	12 (37.5)	8 (25.0)	3 (33.3)	1 (11.1)	29 (33.0)	29 (33.0)
Black or African American	n (%)	5 (10.6)	5 (10.6)	6 (18.8)	5 (15.6)	3 (33.3)	2 (22.2)	14 (15.9)	12 (13.6)
American Indian or Alaska Native	n (%)	0	0	0	0	0	0	0	0
Asian	n (%)	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	n (%)	0	0	0	0	0	0	0	0
Other	n (%)	2 (4.3)	1 (2.1)	1 (3.1)	0	0	0	3 (3.4)	1 (1.1)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Weight (kg)	n	21	26	19	13	6	3	46	42
	Mean (SD)	78.00 (11.559)	79.70 (17.433)	77.97 (10.758)	77.15 (16.598)	67.33 (13.494)	69.23 (6.391)	76.60 (11.793)	78.16 (16.601)
	Median	78.60	83.40	78.50	76.90	66.65	68.40	77.75	76.45
	Min, Max	59.5, 101.9	52.9, 115.3	61.3, 101.0	49.3, 103.2	48.1, 85.8	63.3, 76.0	48.1, 101.9	49.3, 115.3
Height (m)	n	21	26	19	13	6	3	46	42
	Mean (SD)	1.727 (0.0634)	1.681 (0.1035)	1.736 (0.0839)	1.704 (0.1058)	1.727 (0.1078)	1.685 (0.0704)	1.731 (0.0769)	1.688 (0.1008)
	Median	1.727	1.679	1.720	1.716	1.767	1.713	1.729	1.689
	Min, Max	1.59, 1.83	1.49, 1.84	1.60, 1.89	1.53, 1.85	1.53, 1.83	1.61, 1.74	1.53, 1.89	1.49, 1.85

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
BMI (kg/m ²)	n	21	26	19	13	6	3	46	42
	Mean (SD)	26.25 (4.341)	28.02 (4.556)	25.86 (3.139)	26.46 (4.547)	22.40 (2.736)	24.40 (1.610)	25.59 (3.839)	27.28 (4.472)
	Median	26.60	27.20	25.50	26.10	22.05	24.60	25.40	26.80
	Min, Max	20.3, 34.4	19.1, 34.9	22.0, 31.6	18.6, 32.9	19.4, 27.1	22.7, 25.9	19.4, 34.4	18.6, 34.9
Underweight	n (%)	0	0	0	0	0	0	0	0
Normal weight	n (%)	8 (17.0)	5 (10.6)	8 (25.0)	5 (15.6)	5 (55.6)	2 (22.2)	21 (23.9)	12 (13.6)
Overweight	n (%)	9 (19.1)	11 (23.4)	9 (28.1)	4 (12.5)	1 (11.1)	1 (11.1)	19 (21.6)	16 (18.2)
Obese	n (%)	4 (8.5)	10 (21.3)	2 (6.3)	4 (12.5)	0	0	6 (6.8)	14 (15.9)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Waist circumference (cm)	n	21	26	19	13	6	3	46	42
	Mean (SD)	92.6 (13.17)	98.4 (15.92)	91.8 (10.13)	104.9 (27.88)	80.3 (9.38)	85.0 (7.00)	90.7 (12.02)	99.5 (20.24)
	Median	91.0	98.0	91.0	99.0	78.5	85.0	88.0	97.5
	Min, Max	73, 127	73, 149	77, 115	81, 169	73, 98	78, 92	73, 127	73, 169

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 4**

Variable	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
		10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
FTND score	n	21	26	19	13	6	3	46	42
	Mean (SD)	4.9 (2.20)	6.6 (1.95)	5.1 (1.69)	6.5 (1.40)	5.2 (2.57)	7.3 (1.16)	5.0 (2.01)	6.6 (1.73)
	Median	4.0	7.0	5.0	6.0	5.0	8.0	5.0	7.0
	Min, Max	1, 8	1, 10	1, 8	4, 9	2, 8	6, 8	1, 8	1, 10
FTND score									
Mild	n (%)	6 (12.8)	1 (2.1)	3 (9.4)	0	2 (22.2)	0	11 (12.5)	1 (1.1)
Moderate	n (%)	8 (17.0)	11 (23.4)	13 (40.6)	7 (21.9)	2 (22.2)	1 (11.1)	23 (26.1)	19 (21.6)
Severe	n (%)	7 (14.9)	14 (29.8)	3 (9.4)	6 (18.8)	2 (22.2)	2 (22.2)	12 (13.6)	22 (25.0)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 4**

		THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Individual product preference									
THS 2.2 menthol	n (%)	3 (6.4)	4 (8.5)	2 (6.3)	1 (3.1)	2 (22.2)	0	7 (8.0)	5 (5.7)
mCC	n (%)	11 (23.4)	12 (25.5)	11 (34.4)	10 (31.3)	2 (22.2)	3 (33.3)	24 (27.3)	25 (28.4)
SA	n (%)	1 (2.1)	1 (2.1)	0	0	0	0	1 (1.1)	1 (1.1)
No preference	n (%)	6 (12.8)	9 (19.1)	6 (18.8)	2 (6.3)	2 (22.2)	0	14 (15.9)	11 (12.5)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 4**

		THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
Day 4 SES Questionnaire									
SES educational attainment									
Low	n (%)	1 (2.1)	4 (8.5)	0	0	1 (11.1)	0	2 (2.3)	4 (4.5)
Moderate	n (%)	8 (17.0)	7 (14.9)	7 (21.9)	2 (6.3)	2 (22.2)	2 (22.2)	17 (19.3)	11 (12.5)
High	n (%)	12 (25.5)	15 (31.9)	12 (37.5)	11 (34.4)	3 (33.3)	1 (11.1)	27 (30.7)	27 (30.7)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 4**

		THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
SES annual household income									
Low	n (%)	11 (23.4)	9 (19.1)	7 (21.9)	6 (18.8)	5 (55.6)	2 (22.2)	23 (26.1)	17 (19.3)
Moderate	n (%)	4 (8.5)	5 (10.6)	6 (18.8)	1 (3.1)	0	0	10 (11.4)	6 (6.8)
High	n (%)	4 (8.5)	4 (8.5)	3 (9.4)	1 (3.1)	1 (11.1)	1 (11.1)	8 (9.1)	6 (6.8)
Missing	n (%)	2 (4.3)	8 (17.0)	3 (9.4)	5 (15.6)	0	0	5 (5.7)	13 (14.8)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

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**Table 15.2.1.4.3.2 Summary of Demographics and Other Baseline Characteristics by Cigarette Consumption - PP Set****Product Use Time Period: Period 4**

		THSm2.2 (N=47)		mCC (N=32)		SA (N=9)		Overall PP Set (N=88)	
Variable	Statistic	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day	10-19 cig/day	>19 cig/day
SES Composite									
Low	n (%)	0	0	0	0	1 (11.1)	0	1 (1.1)	0
Moderate	n (%)	11 (23.4)	9 (19.1)	7 (21.9)	6 (18.8)	4 (44.4)	2 (22.2)	22 (25.0)	17 (19.3)
High	n (%)	8 (17.0)	9 (19.1)	9 (28.1)	2 (6.3)	1 (11.1)	1 (11.1)	18 (20.5)	12 (13.6)
Missing	n (%)	2 (4.3)	8 (17.0)	3 (9.4)	5 (15.6)	0	0	5 (5.7)	13 (14.8)

Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Height at Screening and body weight and waist circumference at Admission (Day -2) are used.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: BMI = Body Mass Index; FTND = Fagerstrom Test for Nicotine Dependence, SES = Socio-Economic Status.

Appendix 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.12, and 15.3.6.13

Study ID:ZRHM-REXA-08-US Program:t_demog_pp_cc.sas Status: Final

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**Table 15.2.1.5 Summary of Current Cigarette Brands at Screening - Safety Population**

Brand	THSm2.2 (N=80) n (%)	mCC (N=41) n (%)	SA (N=39) n (%)	Product Test (N=5) n (%)	Overall Safety (N=165) n (%)
Newport	12 (15.0)	9 (22.0)	6 (15.4)		27 (16.4)
Marlboro Menthol	7 (8.8)	4 (9.8)	2 (5.1)	1 (20.0)	14 (8.5)
Newport 100's	8 (10.0)	1 (2.4)	2 (5.1)		11 (6.7)
305's Menthol 100's	3 (3.8)	1 (2.4)	2 (5.1)		6 (3.6)
Marlboro Menthol 100's	3 (3.8)	2 (4.9)		1 (20.0)	6 (3.6)
Camel Crush Menthol	2 (2.5)	1 (2.4)	1 (2.6)		4 (2.4)
Marlboro Black Menthol 100's	3 (3.8)		1 (2.6)		4 (2.4)
Other	33 (41.3)	21 (51.2)	19 (48.7)	2 (40.0)	75 (45.5)

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized.

Note: The Overall Safety refers to all subjects in the Safety Population.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Only brands used by at least 4 subjects in the Safety Population are presented.

**Table 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Any medical history	51	(63.8)	183	19	(46.3)	71	26	(66.7)	81	3	(60.0)	17	99	(60.0)	352
Surgical and medical procedures	43	(53.8)	93	16	(39.0)	40	20	(51.3)	45	2	(40.0)	6	81	(49.1)	184
Tooth extraction	28	(35.0)	32	10	(24.4)	11	15	(38.5)	17	0			53	(32.1)	60
Tonsillectomy	8	(10.0)	8	5	(12.2)	5	3	(7.7)	3	1	(20.0)	1	17	(10.3)	17
Caesarean section	7	(8.8)	10	2	(4.9)	4	4	(10.3)	12	0			13	(7.9)	26
Female sterilisation	7	(8.8)	7	1	(2.4)	1	2	(5.1)	2	0			10	(6.1)	10
Hysterectomy	6	(7.5)	6	1	(2.4)	1	1	(2.6)	1	1	(20.0)	1	9	(5.5)	9
Cholecystectomy	2	(2.5)	2	2	(4.9)	2	0			1	(20.0)	1	5	(3.0)	5
Keratomileusis	3	(3.8)	3	1	(2.4)	1	0			0			4	(2.4)	4
Fracture treatment	2	(2.5)	2	0			1	(2.6)	1	0			3	(1.8)	3

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Sterilisation	1	(1.3)	1	1	(2.4)	1	1	(2.6)	1	0			3	(1.8)	3
Abdominal operation	1	(1.3)	1	0			1	(2.6)	1	0			2	(1.2)	2
Abdominoplasty	2	(2.5)	2	0			0			0			2	(1.2)	2
Adenoidectomy	1	(1.3)	1	0			1	(2.6)	1	0			2	(1.2)	2
Appendicectomy	1	(1.3)	1	1	(2.4)	1	0			0			2	(1.2)	2
Myringotomy	0			2	(4.9)	2	0			0			2	(1.2)	2
Oophorectomy	2	(2.5)	2	0			0			0			2	(1.2)	2
Tendon operation	1	(1.3)	1	1	(2.4)	1	0			0			2	(1.2)	2
Ear tube insertion	0			1	(2.4)	3	0			0			1	(0.6)	3
Carpal tunnel decompression	0			1	(2.4)	2	0			0			1	(0.6)	2

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Inguinal hernia repair	0			1	(2.4)	2	0			0			1	(0.6)	2
Rotator cuff repair	1	(1.3)	2	0			0			0			1	(0.6)	2
Spinal fusion surgery	1	(1.3)	2	0			0			0			1	(0.6)	2
Benign breast lump removal	0			0			1	(2.6)	1	0			1	(0.6)	1
Breast operation	0			1	(2.4)	1	0			0			1	(0.6)	1
Breast prosthesis implantation	1	(1.3)	1	0			0			0			1	(0.6)	1
Cyst removal	0			1	(2.4)	1	0			0			1	(0.6)	1
Elbow operation	0			1	(2.4)	1	0			0			1	(0.6)	1
Exploratory operation	0			0			1	(2.6)	1	0			1	(0.6)	1
Eye operation	1	(1.3)	1	0			0			0			1	(0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Gastrointestinal surgery	0			0			1	(2.6)	1	0			1	(0.6)	1
Hand repair operation	1	(1.3)	1	0			0			0			1	(0.6)	1
Intervertebral disc operation	0			0			0			1	(20.0)	1	1	(0.6)	1
Limb operation	1	(1.3)	1	0			0			0			1	(0.6)	1
Mammoplasty	0			0			0			1	(20.0)	1	1	(0.6)	1
Nail operation	1	(1.3)	1	0			0			0			1	(0.6)	1
Salpingo-oophorectomy bilateral	0			0			0			1	(20.0)	1	1	(0.6)	1
Shoulder arthroplasty	0			0			1	(2.6)	1	0			1	(0.6)	1
Small intestine operation	1	(1.3)	1	0			0			0			1	(0.6)	1
Splenectomy	1	(1.3)	1	0			0			0			1	(0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Suture insertion	1	(1.3)	1	0			0			0			1	(0.6)	1
Testicular operation	0			0			1	(2.6)	1	0			1	(0.6)	1
Transfusion	1	(1.3)	1	0			0			0			1	(0.6)	1
Vasectomy	1	(1.3)	1	0			0			0			1	(0.6)	1
Vocal cord polypectomy	0			0			1	(2.6)	1	0			1	(0.6)	1
Injury, poisoning and procedural complications	16	(20.0)	22	6	(14.6)	8	9	(23.1)	11	1	(20.0)	1	32	(19.4)	42
Hand fracture	5	(6.3)	5	0			1	(2.6)	1	0			6	(3.6)	6
Wrist fracture	1	(1.3)	2	1	(2.4)	1	3	(7.7)	4	0			5	(3.0)	7
Ankle fracture	2	(2.5)	2	0			0			1	(20.0)	1	3	(1.8)	3
Clavicle fracture	0			1	(2.4)	1	2	(5.1)	2	0			3	(1.8)	3

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Lower limb fracture	2	(2.5)	2	0			1	(2.6)	1	0			3	(1.8)	3
Upper limb fracture	1	(1.3)	1	2	(4.9)	2	0			0			3	(1.8)	3
Gun shot wound	1	(1.3)	2	0			1	(2.6)	1	0			2	(1.2)	3
Femur fracture	1	(1.3)	1	0			1	(2.6)	1	0			2	(1.2)	2
Foot fracture	1	(1.3)	1	0			1	(2.6)	1	0			2	(1.2)	2
Laceration	2	(2.5)	2	0			0			0			2	(1.2)	2
Tendon rupture	1	(1.3)	1	1	(2.4)	1	0			0			2	(1.2)	2
Facial bones fracture	0			1	(2.4)	1	0			0			1	(0.6)	1
Limb injury	1	(1.3)	1	0			0			0			1	(0.6)	1
Multiple fractures	1	(1.3)	1	0			0			0			1	(0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Road traffic accident	0			1	(2.4)	1	0			0			1	(0.6)	1
Spinal fracture	1	(1.3)	1	0			0			0			1	(0.6)	1
Traumatic haemorrhage	0			1	(2.4)	1	0			0			1	(0.6)	1
Pregnancy, puerperium and perinatal conditions	14	(17.5)	32	1	(2.4)	3	5	(12.8)	8	2	(40.0)	3	22	(13.3)	46
Delivery	13	(16.3)	26	1	(2.4)	3	4	(10.3)	7	1	(20.0)	2	19	(11.5)	38
Ectopic pregnancy	2	(2.5)	2	0			1	(2.6)	1	0			3	(1.8)	3
Abortion spontaneous	1	(1.3)	3	0			0			0			1	(0.6)	3
Placenta praevia	1	(1.3)	1	0			0			0			1	(0.6)	1
Pregnancy	0			0			0			1	(20.0)	1	1	(0.6)	1
Infections and infestations	8	(10.0)	8	8	(19.5)	9	4	(10.3)	4	0			20	(12.1)	21

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Oral herpes	1	(1.3)	1	0			1	(2.6)	1				2	(1.2)	2
Pneumonia	0			2	(4.9)	2	0						2	(1.2)	2
Urinary tract infection	0			1	(2.4)	1	1	(2.6)	1				2	(1.2)	2
Amoebiasis	0			0			1	(2.6)	1				1	(0.6)	1
Appendicitis	1	(1.3)	1	0			0						1	(0.6)	1
Chlamydial infection	0			1	(2.4)	1	0						1	(0.6)	1
Folliculitis	1	(1.3)	1	0			0						1	(0.6)	1
Furuncle	1	(1.3)	1	0			0						1	(0.6)	1
Influenza	0			1	(2.4)	1	0						1	(0.6)	1
Kidney infection	1	(1.3)	1	0			0						1	(0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Mononucleosis syndrome	1	(1.3)	1	0			0						1	(0.6)	1
Nasopharyngitis	0			1	(2.4)	1	0						1	(0.6)	1
Otitis media	0			1	(2.4)	1	0						1	(0.6)	1
Staphylococcal infection	0			0			1	(2.6)	1				1	(0.6)	1
Tonsillitis	0			1	(2.4)	1	0						1	(0.6)	1
Tuberculosis	1	(1.3)	1	0			0						1	(0.6)	1
Upper respiratory tract infection	0			1	(2.4)	1	0						1	(0.6)	1
Vaginal infection	1	(1.3)	1	0			0						1	(0.6)	1
Nervous system disorders	5	(6.3)	5	0			0			0			5	(3.0)	5
Tension headache	2	(2.5)	2										2	(1.2)	2

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Carpal tunnel syndrome	1	(1.3)	1										1	(0.6)	1
Coma	1	(1.3)	1										1	(0.6)	1
Headache	1	(1.3)	1										1	(0.6)	1
Psychiatric disorders	0			2	(4.9)	3	1	(2.6)	2	1	(20.0)	2	4	(2.4)	7
Anxiety				1	(2.4)	1	1	(2.6)	1	0			2	(1.2)	2
Depression				1	(2.4)	1	1	(2.6)	1	0			2	(1.2)	2
Attention deficit/hyperactivity disorder				0			0			1	(20.0)	2	1	(0.6)	2
Insomnia				1	(2.4)	1	0			0			1	(0.6)	1
Eye disorders	2	(2.5)	3	2	(4.9)	3	0			0			4	(2.4)	6
Myopia	2	(2.5)	2	1	(2.4)	1							3	(1.8)	3

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Astigmatism	1	(1.3)	1	1	(2.4)	1							2	(1.2)	2
Presbyopia	0			1	(2.4)	1							1	(0.6)	1
Immune system disorders	3	(3.8)	3	1	(2.4)	1	0			0			4	(2.4)	4
Drug hypersensitivity	3	(3.8)	3	0									3	(1.8)	3
Multiple allergies	0			1	(2.4)	1							1	(0.6)	1
Musculoskeletal and connective tissue disorders	3	(3.8)	3	0			0			1	(20.0)	1	4	(2.4)	4
Back pain	0									1	(20.0)	1	1	(0.6)	1
Bone disorder	1	(1.3)	1							0			1	(0.6)	1
Myalgia	1	(1.3)	1							0			1	(0.6)	1
Rotator cuff syndrome	1	(1.3)	1							0			1	(0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	(2.5)	2	0			1	(2.6)	1	1	(20.0)	1	4	(2.4)	4
Adenoma benign	0						1	(2.6)	1	0			1	(0.6)	1
Benign breast neoplasm	1	(1.3)	1				0			0			1	(0.6)	1
Ovarian cancer	0						0			1	(20.0)	1	1	(0.6)	1
Skin papilloma	1	(1.3)	1				0			0			1	(0.6)	1
Reproductive system and breast disorders	2	(2.5)	2	0			2	(5.1)	2	0			4	(2.4)	4
Endometriosis	1	(1.3)	1				0						1	(0.6)	1
Fibrocystic breast disease	0						1	(2.6)	1				1	(0.6)	1
Ovarian cyst	1	(1.3)	1				0						1	(0.6)	1
Testicular cyst	0						1	(2.6)	1				1	(0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Respiratory, thoracic and mediastinal disorders	1	(1.3)	1	2	(4.9)	2	1	(2.6)	1	0			4	(2.4)	4
Asthma	0			0			1	(2.6)	1				1	(0.6)	1
Bronchitis chronic	0			1	(2.4)	1	0						1	(0.6)	1
Infantile asthma	1	(1.3)	1	0			0						1	(0.6)	1
Oropharyngeal pain	0			1	(2.4)	1	0						1	(0.6)	1
Skin and subcutaneous tissue disorders	2	(2.5)	2	0			2	(5.1)	2	0			4	(2.4)	4
Acne	0						1	(2.6)	1				1	(0.6)	1
Chloasma	0						1	(2.6)	1				1	(0.6)	1
Dry skin	1	(1.3)	1				0						1	(0.6)	1
Ingrowing nail	1	(1.3)	1				0						1	(0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Investigations	2	(2.5)	2	0			1	(2.6)	3	0			3	(1.8)	5
Biopsy breast	1	(1.3)	1				1	(2.6)	3				2	(1.2)	4
Arthroscopy	1	(1.3)	1				0						1	(0.6)	1
Social circumstances	2	(2.5)	2	1	(2.4)	1	0			0			3	(1.8)	3
Blood donor	0			1	(2.4)	1							1	(0.6)	1
Breast prosthesis user	1	(1.3)	1	0									1	(0.6)	1
Denture wearer	1	(1.3)	1	0									1	(0.6)	1
Blood and lymphatic system disorders	0			0			1	(2.6)	1	1	(20.0)	1	2	(1.2)	2
Anaemia							1	(2.6)	1	0			1	(0.6)	1
Leukocytosis							0			1	(20.0)	1	1	(0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Hepatobiliary disorders	0			1	(2.4)	1	0			1	(20.0)	1	2	(1.2)	2
Cholelithiasis				1	(2.4)	1				0			1	(0.6)	1
Reye's syndrome				0						1	(20.0)	1	1	(0.6)	1
Congenital, familial and genetic disorders	0			0			0			1	(20.0)	1	1	(0.6)	1
Thalassaemia										1	(20.0)	1	1	(0.6)	1
Ear and labyrinth disorders	1	(1.3)	1	0			0			0			1	(0.6)	1
Otorrhoea	1	(1.3)	1										1	(0.6)	1
Endocrine disorders	1	(1.3)	1	0			0			0			1	(0.6)	1
Hyperthyroidism	1	(1.3)	1										1	(0.6)	1
Gastrointestinal disorders	0			0			1	(2.6)	1	0			1	(0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.6 Summary of Medical History - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Tooth loss							1	(2.6)	1				1	(0.6)	1
General disorders and administration site conditions	1	(1.3)	1	0			0			0			1	(0.6)	1
Device failure	1	(1.3)	1										1	(0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Appendix 15.3.1.9.

Study ID: ZRHM-REXA-08-US

Program: t_medhis.sas

Status: Final

21SEP15

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**Table 15.2.1.7 Summary of Concomitant Diseases - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Any concomitant disease	50	(62.5)	87	25	(61.0)	59	26	(66.7)	58	2	(40.0)	8	103	(62.4)	212
Eye disorders	18	(22.5)	19	9	(22.0)	9	12	(30.8)	13	0			39	(23.6)	41
Myopia	5	(6.3)	5	5	(12.2)	5	7	(17.9)	7				17	(10.3)	17
Presbyopia	7	(8.8)	7	2	(4.9)	2	3	(7.7)	3				12	(7.3)	12
Astigmatism	1	(1.3)	1	0			2	(5.1)	2				3	(1.8)	3
Hypermetropia	1	(1.3)	1	1	(2.4)	1	1	(2.6)	1				3	(1.8)	3
Blindness unilateral	1	(1.3)	1	1	(2.4)	1	0		0				2	(1.2)	2
Visual impairment	2	(2.5)	2	0			0		0				2	(1.2)	2
Conjunctival hyperaemia	1	(1.3)	1	0			0		0				1	(0.6)	1
Ocular hyperaemia	1	(1.3)	1	0			0		0				1	(0.6)	1

Note: "Product Test" refers to all subjects tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC =Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.7 Summary of Concomitant Diseases - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Immune system disorders	15	(18.8)	18	10	(24.4)	12	8	(20.5)	8	1	(20.0)	1	34	(20.6)	39
Seasonal allergy	7	(8.8)	7	7	(17.1)	7	3	(7.7)	3	0			17	(10.3)	17
Drug hypersensitivity	6	(7.5)	7	2	(4.9)	2	3	(7.7)	3	1	(20.0)	1	12	(7.3)	13
Allergy to animal	3	(3.8)	3	0			0			0			3	(1.8)	3
Food allergy	1	(1.3)	1	1	(2.4)	1	1	(2.6)	1	0			3	(1.8)	3
Allergy to arthropod bite	0			0			1	(2.6)	1	0			1	(0.6)	1
Allergy to arthropod sting	0			1	(2.4)	1	0			0			1	(0.6)	1
Allergy to metals	0			1	(2.4)	1	0			0			1	(0.6)	1
Social circumstances	7	(8.8)	10	2	(4.9)	2	7	(17.9)	8	2	(40.0)	3	18	(10.9)	23
Corrective lens user	3	(3.8)	3	1	(2.4)	1	3	(7.7)	3	1	(20.0)	1	8	(4.8)	8

Note: "Product Test" refers to all subjects tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC =Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.7 Summary of Concomitant Diseases - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Tattoo	2	(2.5)	2	1	(2.4)	1	1	(2.6)	1	1	(20.0)	1	5	(3.0)	5
Breast prosthesis user	3	(3.8)	3	0			1	(2.6)	1	0			4	(2.4)	4
Denture wearer	0			0			2	(5.1)	2	0			2	(1.2)	2
Postmenopause	1	(1.3)	1	0			1	(2.6)	1	0			2	(1.2)	2
Cosmetic body piercing	1	(1.3)	1	0			0			0			1	(0.6)	1
Edentulous	0			0			0			1	(20.0)	1	1	(0.6)	1
Skin and subcutaneous tissue disorders	8	(10.0)	8	5	(12.2)	5	4	(10.3)	5	0			17	(10.3)	18
Acne	7	(8.8)	7	4	(9.8)	4	1	(2.6)	1				12	(7.3)	12
Keloid scar	0			0			1	(2.6)	2				1	(0.6)	2
Dermal cyst	0			0			1	(2.6)	1				1	(0.6)	1

Note: "Product Test" refers to all subjects tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC =Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.7 Summary of Concomitant Diseases - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Dry skin	1	(1.3)	1	0			0						1	(0.6)	1
Hirsutism	0			0			1	(2.6)	1				1	(0.6)	1
Skin lesion	0			1	(2.4)	1	0						1	(0.6)	1
Gastrointestinal disorders	4	(5.0)	5	4	(9.8)	4	6	(15.4)	7	1	(20.0)	1	15	(9.1)	17
Dental caries	2	(2.5)	2	1	(2.4)	1	2	(5.1)	2	0			5	(3.0)	5
Tooth loss	0			2	(4.9)	2	2	(5.1)	2	1	(20.0)	1	5	(3.0)	5
Toothache	1	(1.3)	1	0			1	(2.6)	1	0			2	(1.2)	2
Dyspepsia	1	(1.3)	2	0			0			0			1	(0.6)	2
Gastrooesophageal reflux disease	0			0			1	(2.6)	1	0			1	(0.6)	1
Inguinal hernia	0			0			1	(2.6)	1	0			1	(0.6)	1

Note: "Product Test" refers to all subjects tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC =Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.7 Summary of Concomitant Diseases - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Nausea	0			1	(2.4)	1	0			0			1	(0.6)	1
Injury, poisoning and procedural complications	3	(3.8)	3	6	(14.6)	8	1	(2.6)	1	1	(20.0)	2	11	(6.7)	14
Tooth fracture	2	(2.5)	2	2	(4.9)	2	1	(2.6)	1	0			5	(3.0)	5
Scar	0			2	(4.9)	4	0			1	(20.0)	1	3	(1.8)	5
Laceration	1	(1.3)	1	0			0			1	(20.0)	1	2	(1.2)	2
Ligament sprain	0			1	(2.4)	1	0			0			1	(0.6)	1
Post-traumatic neck syndrome	0			1	(2.4)	1	0			0			1	(0.6)	1
Nervous system disorders	4	(5.0)	4	4	(9.8)	4	2	(5.1)	2	0			10	(6.1)	10
Tension headache	3	(3.8)	3	2	(4.9)	2	1	(2.6)	1				6	(3.6)	6
Headache	1	(1.3)	1	1	(2.4)	1	0						2	(1.2)	2

Note: "Product Test" refers to all subjects tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC =Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.7 Summary of Concomitant Diseases - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Migraine	0			1	(2.4)	1	0						1	(0.6)	1
Sinus headache	0			0			1	(2.6)	1				1	(0.6)	1
Investigations	3	(3.8)	3	4	(9.8)	4	1	(2.6)	1	0			8	(4.8)	8
Lymphocyte count increased	2	(2.5)	2	1	(2.4)	1	0						3	(1.8)	3
Neutrophil count decreased	0			1	(2.4)	1	1	(2.6)	1				2	(1.2)	2
Blood cholesterol increased	0			1	(2.4)	1	0						1	(0.6)	1
Blood triglycerides increased	0			1	(2.4)	1	0						1	(0.6)	1
Gamma-glutamyltransferase increased	1	(1.3)	1	0			0						1	(0.6)	1
Reproductive system and breast disorders	3	(3.8)	4	1	(2.4)	1	3	(7.7)	3	0			7	(4.2)	8
Dysmenorrhoea	2	(2.5)	2	0			2	(5.1)	2				4	(2.4)	4

Note: "Product Test" refers to all subjects tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC =Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.7 Summary of Concomitant Diseases - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Fibrocystic breast disease	1	(1.3)	1	1	(2.4)	1	0						2	(1.2)	2
Breast mass	1	(1.3)	1	0			0						1	(0.6)	1
Ovarian cyst	0			0			1	(2.6)	1				1	(0.6)	1
Respiratory, thoracic and mediastinal disorders	2	(2.5)	2	4	(9.8)	4	0			0			6	(3.6)	6
Asthma	0			2	(4.9)	2							2	(1.2)	2
Cough	2	(2.5)	2	0									2	(1.2)	2
Lung disorder	0			1	(2.4)	1							1	(0.6)	1
Sinus congestion	0			1	(2.4)	1							1	(0.6)	1
Musculoskeletal and connective tissue disorders	2	(2.5)	2	0			3	(7.7)	3	0			5	(3.0)	5
Back pain	0						2	(5.1)	2				2	(1.2)	2

Note: "Product Test" refers to all subjects tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC =Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.7 Summary of Concomitant Diseases - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Fibromyalgia	1	(1.3)	1				0						1	(0.6)	1
Limb deformity	1	(1.3)	1				0						1	(0.6)	1
Musculoskeletal pain	0						1	(2.6)	1				1	(0.6)	1
Metabolism and nutrition disorders	0			1	(2.4)	1	2	(5.1)	2	1	(20.0)	1	4	(2.4)	4
Lactose intolerance				0			2	(5.1)	2	0			2	(1.2)	2
Hyperkalaemia				1	(2.4)	1	0			0			1	(0.6)	1
Type 2 diabetes mellitus				0			0			1	(20.0)	1	1	(0.6)	1
Surgical and medical procedures	3	(3.8)	3	0			0			0			3	(1.8)	3
Artificial crown procedure	2	(2.5)	2										2	(1.2)	2
Caesarean section	1	(1.3)	1										1	(0.6)	1

Note: "Product Test" refers to all subjects tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC =Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.7 Summary of Concomitant Diseases - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	(1.3)	2	0			1	(2.6)	1	0			2	(1.2)	3
Uterine leiomyoma	1	(1.3)	1				1	(2.6)	1				2	(1.2)	2
Angiofibroma	1	(1.3)	1				0						1	(0.6)	1
Cardiac disorders	1	(1.3)	1	0			1	(2.6)	1	0			2	(1.2)	2
Mitral valve prolapse	0						1	(2.6)	1				1	(0.6)	1
Palpitations	1	(1.3)	1				0						1	(0.6)	1
Congenital, familial and genetic disorders	2	(2.5)	2	0			0			0			2	(1.2)	2
Birth mark	1	(1.3)	1										1	(0.6)	1
Syndactyly	1	(1.3)	1										1	(0.6)	1
Infections and infestations	1	(1.3)	1	0			1	(2.6)	1	0			2	(1.2)	2

Note: "Product Test" refers to all subjects tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC =Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.7 Summary of Concomitant Diseases - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Oral herpes	1	(1.3)	1				1	(2.6)	1				2	(1.2)	2
Psychiatric disorders	0			1	(2.4)	1	1	(2.6)	1	0			2	(1.2)	2
Insomnia				0			1	(2.6)	1				1	(0.6)	1
Panic attack				1	(2.4)	1	0						1	(0.6)	1
Renal and urinary disorders	0			2	(4.9)	2	0			0			2	(1.2)	2
Nephrolithiasis				2	(4.9)	2							2	(1.2)	2
Endocrine disorders	0			1	(2.4)	1	0			0			1	(0.6)	1
Hypothyroidism				1	(2.4)	1							1	(0.6)	1
General disorders and administration site conditions	0			0			1	(2.6)	1	0			1	(0.6)	1
Pain							1	(2.6)	1				1	(0.6)	1

Note: "Product Test" refers to all subjects tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC =Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.1.7 Summary of Concomitant Diseases - Safety Population**

System Organ Class Preferred Term	THSm2.2 (N=80)			mCC (N=41)			SA (N=39)			Product Test (N=5)			Overall Safety (N=165)		
	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events	n	(%)	Events
Vascular disorders	0			1	(2.4)	1	0			0			1	(0.6)	1
Hypertension				1	(2.4)	1							1	(0.6)	1

Note: "Product Test" refers to all subjects tested the THS product but were not randomized.

Note: The "Overall Safety" refers to all subjects in the Safety Population.

Note: mCC =Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).



15.2.2 Product Use Tables

**Table 15.2.2.1.1 Summary of Daily Product Use in Confinement Period- FAS**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
THSm2.2 Test	Day -2	1	n(%)	69 (86.3)	32 (78.0)	35 (89.7)	136 (85.0)
		2	n(%)	7 (8.8)	7 (17.1)	4 (10.3)	18 (11.3)
		3	n(%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		4	n(%)	0	1 (2.4)	0	1 (0.6)
	Day -2	THSm2.2	n	79	41	39	159
			Mean (SD)	1.1 (0.42)	1.3 (0.65)	1.1 (0.31)	1.2 (0.47)
			95% CI	1.0, 1.3	1.0, 1.5	1.0, 1.3	1.0, 1.3
			Median	1.0	1.0	1.0	1.0
			Min, Max	1, 3	1, 4	1, 2	1, 4

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.1 Summary of Daily Product Use in Confinement Period- FAS**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Pre-Randomization Period	Day -1	mCC/CC	n	79	41	39	159
			Mean (SD)	13.2 (4.04)	13.8 (3.50)	13.3 (3.93)	13.4 (3.86)
			95% CI	12.2, 14.2	12.7, 15.0	12.0, 14.7	12.7, 14.0
			Median	13.0	13.0	13.0	13.0
			Min, Max	3, 24	8, 21	5, 22	3, 24
	Day -1	THSm2.2	n	0	0	0	0
			Mean (SD)				
			95% CI				
			Median				
			Min, Max				

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.1 Summary of Daily Product Use in Confinement Period- FAS**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Pre-Randomization Period	Day 0	mCC/CC	n	79	41	39	159
			Mean (SD)	12.1 (3.62)	12.6 (3.11)	12.3 (3.61)	12.3 (3.48)
			95% CI	11.2, 13.0	11.5, 13.6	11.1, 13.6	11.7, 12.9
			Median	11.0	12.0	12.0	12.0
			Min, Max	6, 20	6, 20	6, 20	6, 20
	Day 0	THSm2.2	n	0	0	0	0
			Mean (SD)				
			95% CI				
			Median				
			Min, Max				

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.1 Summary of Daily Product Use in Confinement Period- FAS**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Randomization Period	Day 1	mCC/CC	n	0	41	0	41
			Mean (SD)		11.5 (3.37)		11.5 (3.37)
			95% CI		10.4, 12.6		10.4, 12.6
			Median		12.0		12.0
			Min, Max		4, 19		4, 19
	Day 1	THSm2.2	n	79	0	0	79
			Mean (SD)	12.5 (4.60)			12.5 (4.60)
			95% CI	11.4, 13.6			11.4, 13.6
			Median	12.0			12.0
			Min, Max	3, 23			3, 23

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.1 Summary of Daily Product Use in Confinement Period- FAS**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Randomization Period	Day 2	mCC/CC	n	0	40	0	40
			Mean (SD)		12.4 (3.69)		12.4 (3.69)
			95% CI		11.2, 13.6		11.2, 13.6
			Median		12.0		12.0
			Min, Max		6, 21		6, 21
	Day 2	THSm2.2	n	79	0	0	79
			Mean (SD)	13.7 (4.85)			13.7 (4.85)
			95% CI	12.6, 14.8			12.6, 14.8
			Median	12.0			12.0
			Min, Max	3, 26			3, 26

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.1 Summary of Daily Product Use in Confinement Period- FAS**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Randomization Period	Day 3	mCC/CC	n	0	40	0	40
			Mean (SD)		12.6 (3.38)		12.6 (3.38)
			95% CI		11.5, 13.7		11.5, 13.7
			Median		12.0		12.0
			Min, Max		7, 20		7, 20
	Day 3	THSm2.2	n	79	0	0	79
			Mean (SD)	14.9 (5.22)			14.9 (5.22)
			95% CI	13.6, 16.1			13.6, 16.1
			Median	14.0			14.0
			Min, Max	3, 28			3, 28

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.1 Summary of Daily Product Use in Confinement Period- FAS**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Randomization Period	Day 4	mCC/CC	n	0	40	0	40
			Mean (SD)		12.2 (3.16)		12.2 (3.16)
			95% CI		11.1, 13.2		11.1, 13.2
			Median		12.0		12.0
			Min, Max		7, 18		7, 18
	Day 4	THSm2.2	n	79	0	0	79
			Mean (SD)	14.5 (5.08)			14.5 (5.08)
			95% CI	13.3, 15.7			13.3, 15.7
			Median	14.0			14.0
			Min, Max	1, 26			1, 26

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.1 Summary of Daily Product Use in Confinement Period- FAS**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Randomization Period	Day 5	mCC/CC	n	0	40	0	40
			Mean (SD)		13.9 (4.08)		13.9 (4.08)
			95% CI		12.6, 15.3		12.6, 15.3
			Median		14.5		14.5
			Min, Max		7, 23		7, 23
	Day 5	THSm2.2	n	79	0	0	79
			Mean (SD)	16.4 (5.66)			16.4 (5.66)
			95% CI	15.1, 17.7			15.1, 17.7
			Median	16.0			16.0
			Min, Max	2, 31			2, 31

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.1 Summary of Daily Product Use in Confinement Period- FAS**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Randomization Period	Day 6	mCC/CC	n	0	39	0	39
			Mean (SD)		3.1 (1.58)		3.1 (1.58)
			95% CI		2.5, 3.6		2.5, 3.6
			Median		3.0		3.0
			Min, Max		1, 7		1, 7
	Day 6	THSm2.2	n	77	0	0	77
			Mean (SD)	3.8 (1.81)			3.8 (1.81)
			95% CI	3.3, 4.2			3.3, 4.2
			Median	3.0			3.0
			Min, Max	1, 10			1, 10

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.2 Summary of Daily Product Use in Confinement Period- PP Set**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
THSm2.2 Test	Day -2	1	n(%)	66 (88.0)	26 (74.3)	20 (83.3)	112 (83.6)
		2	n(%)	7 (9.3)	7 (20.0)	4 (16.7)	18 (13.4)
		3	n(%)	2 (2.7)	1 (2.9)	0	3 (2.2)
		4	n(%)	0	1 (2.9)	0	1 (0.7)
	Day -2	THSm2.2	n	75	35	24	134
			Mean (SD)	1.2 (0.43)	1.3 (0.69)	1.2 (0.39)	1.2 (0.51)
			95% CI	1.0, 1.3	1.1, 1.6	1.0, 1.4	1.1, 1.3
			Median	1.0	1.0	1.0	1.0
			Min, Max	1, 3	1, 4	1, 2	1, 4

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.2 Summary of Daily Product Use in Confinement Period- PP Set**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
Pre-Randomization Period	Day -1	mCC	n	75	35	24	134
			Mean (SD)	13.3 (4.11)	13.7 (3.50)	12.8 (3.98)	13.3 (3.92)
			95% CI	12.3, 14.3	12.5, 15.0	11.1, 14.6	12.6, 14.0
			Median	13.0	13.0	12.0	13.0
			Min, Max	3, 24	8, 21	5, 21	3, 24
	Day -1	THSm2.2	n	0	0	0	0
			Mean (SD)				
			95% CI				
			Median				
			Min, Max				

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.2 Summary of Daily Product Use in Confinement Period- PP Set**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
Pre-Randomization Period	Day 0	mCC/CC	n	75	35	24	134
			Mean (SD)	12.2 (3.68)	12.2 (3.01)	11.6 (3.40)	12.1 (3.45)
			95% CI	11.3, 13.1	11.1, 13.3	10.1, 13.1	11.4, 12.7
			Median	11.0	12.0	11.0	11.0
			Min, Max	6, 20	6, 19	6, 19	6, 20
	Day 0	THSm2.2	n	0	0	0	0
			Mean (SD)				
			95% CI				
			Median				
			Min, Max				

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.2 Summary of Daily Product Use in Confinement Period- PP Set**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
Randomization Period	Day 1	mCC/CC	n	0	35	0	35
			Mean (SD)		11.3 (3.28)		11.3 (3.28)
			95% CI		10.1, 12.5		10.1, 12.5
			Median		11.0		11.0
			Min, Max		4, 19		4, 19
	Day 1	THSm2.2	n	75	0	0	75
			Mean (SD)	12.5 (4.68)			12.5 (4.68)
			95% CI	11.4, 13.6			11.4, 13.6
			Median	12.0			12.0
			Min, Max	3, 23			3, 23

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.2 Summary of Daily Product Use in Confinement Period- PP Set**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
Randomization Period	Day 2	mCC/CC	n	0	34	0	34
			Mean (SD)		12.0 (3.68)		12.0 (3.68)
			95% CI		10.7, 13.4		10.7, 13.4
			Median		11.5		11.5
			Min, Max		6, 21		6, 21
	Day 2	THSm2.2	n	75	0	0	75
			Mean (SD)	13.7 (4.96)			13.7 (4.96)
			95% CI	12.5, 14.9			12.5, 14.9
			Median	12.0			12.0
			Min, Max	3, 26			3, 26

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.2 Summary of Daily Product Use in Confinement Period- PP Set**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
Randomization Period	Day 3	mCC/CC	n	0	34	0	34
			Mean (SD)		12.2 (3.27)		12.2 (3.27)
			95% CI		11.0, 13.4		11.0, 13.4
			Median		12.0		12.0
			Min, Max		7, 20		7, 20
	Day 3	THSm2.2	n	75	0	0	75
			Mean (SD)	15.0 (5.27)			15.0 (5.27)
			95% CI	13.7, 16.3			13.7, 16.3
			Median	14.0			14.0
			Min, Max	3, 28			3, 28

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.2 Summary of Daily Product Use in Confinement Period- PP Set**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
Randomization Period	Day 4	mCC/CC	n	0	34	0	34
			Mean (SD)		11.9 (3.25)		11.9 (3.25)
			95% CI		10.7, 13.1		10.7, 13.1
			Median		11.5		11.5
			Min, Max		7, 18		7, 18
	Day 4	THSm2.2	n	75	0	0	75
			Mean (SD)	14.6 (5.19)			14.6 (5.19)
			95% CI	13.3, 15.8			13.3, 15.8
			Median	14.0			14.0
			Min, Max	1, 26			1, 26

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.2 Summary of Daily Product Use in Confinement Period- PP Set**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
Randomization Period	Day 5	mCC/CC	n	0	34	0	34
			Mean (SD)		13.7 (4.11)		13.7 (4.11)
			95% CI		12.2, 15.1		12.2, 15.1
			Median		14.0		14.0
			Min, Max		7, 23		7, 23
	Day 5	THSm2.2	n	75	0	0	75
			Mean (SD)	16.5 (5.77)			16.5 (5.77)
			95% CI	15.1, 17.9			15.1, 17.9
			Median	16.0			16.0
			Min, Max	2, 31			2, 31

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.1.2 Summary of Daily Product Use in Confinement Period- PP Set**

Occasion	Visit	Number of Uses	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)	Overall PP Set (N=134)
Randomization Period	Day 6	mCC/CC	n	0	33	0	33
			Mean (SD)		2.8 (1.22)		2.8 (1.22)
			95% CI		2.3, 3.3		2.3, 3.3
			Median		3.0		3.0
			Min, Max		1, 6		1, 6
	Day 6	THSm2.2	n	73	0	0	73
			Mean (SD)	3.8 (1.83)			3.8 (1.83)
			95% CI	3.3, 4.2			3.3, 4.2
			Median	3.0			3.0
			Min, Max	1, 10			1, 10

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: n represents the number of reporting subjects.

Note: Confinement period is defined as period from Day -2 to Day 6.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
THSm2.2 Sticks	Period 2	n(%)	80 (100)	0	0	80 (50.0)
		Mean (SD)	18.5 (10.24)			18.5 (10.24)
		95% CI	16.2, 20.8			16.2, 20.8
		Median	17.0			17.0
		Min, Max	2, 68			2, 68
THSm2.2 Sticks	Period 3	n(%)	79 (98.8)	0	0	79 (49.4)
		Mean (SD)	18.2 (10.44)			18.2 (10.44)
		95% CI	15.8, 20.6			15.8, 20.6
		Median	16.0			16.0
		Min, Max	0, 60			0, 60

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
THSm2.2 Sticks	Period 4	n(%)	76 (95.0)	0	0	76 (47.5)
		Mean (SD)	17.2 (9.75)			17.2 (9.75)
		95% CI	14.9, 19.5			14.9, 19.5
		Median	16.0			16.0
		Min, Max	0, 51			0, 51
THSm2.2 Sticks	Ambulatory	n(%)	80 (100)	0	0	80 (50.0)
		Mean (SD)	20.7 (11.47)			20.7 (11.47)
		95% CI	18.1, 23.3			18.1, 23.3
		Median	20.0			20.0
		Min, Max	2, 68			2, 68

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
mCC/CC	Period 2	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	4.5 (6.07)	21.1 (7.48)	4.8 (6.96)	8.9 (9.81)
		95% CI	3.1, 5.9	18.6, 23.5	2.3, 7.3	7.3, 10.5
		Median	0.5	20.0	2.0	5.0
		Min, Max	0, 24	11, 43	0, 31	0, 43
mCC/CC	Period 3	n(%)	79 (98.8)	39 (95.1)	31 (79.5)	149 (93.1)
		Mean (SD)	3.5 (5.09)	21.3 (8.72)	6.1 (8.80)	8.7 (10.35)
		95% CI	2.3, 4.6	18.5, 24.2	2.8, 9.3	7.0, 10.4
		Median	0.0	20.0	3.0	5.0
		Min, Max	0, 20	11, 42	0, 41	0, 42

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
mCC/CC	Period 4	n(%)	76 (95.0)	36 (87.8)	30 (76.9)	142 (88.8)
		Mean (SD)	3.0 (5.27)	20.9 (7.30)	5.9 (7.46)	8.2 (9.81)
		95% CI	1.8, 4.3	18.4, 23.4	3.1, 8.8	6.5, 9.9
		Median	0.0	20.0	3.5	3.5
		Min, Max	0, 23	12, 40	0, 34	0, 40
mCC/CC	Ambulatory	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	5.4 (6.61)	22.7 (8.51)	7.6 (9.41)	10.4 (10.70)
		95% CI	3.9, 6.9	19.9, 25.4	4.2, 10.9	8.6, 12.1
		Median	2.0	21.0	5.0	8.0
		Min, Max	0, 24	12, 43	0, 41	0, 43

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Chew/Smokeless Tob.	Period 2	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0
Chew/Smokeless Tob.	Period 3	n(%)	79 (98.8)	39 (95.1)	31 (79.5)	149 (93.1)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Chew/Smokeless Tob.	Period 4	n(%)	76 (95.0)	36 (87.8)	30 (76.9)	142 (88.8)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0
Chew/Smokeless Tob.	Ambulatory	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Cigar/Cigarillo	Period 2	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0
Cigar/Cigarillo	Period 3	n(%)	79 (98.8)	39 (95.1)	31 (79.5)	149 (93.1)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Cigar/Cigarillo	Period 4	n(%)	76 (95.0)	36 (87.8)	30 (76.9)	142 (88.8)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.1 (0.37)	0.0 (0.17)
		95% CI	NC, NC	NC, NC	-0.1, 0.3	-0.1, 0.1
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 2	0, 2
Cigar/Cigarillo	Ambulatory	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.1 (0.35)	0.0 (0.17)
		95% CI	NC, NC	NC, NC	-0.1, 0.2	-0.1, 0.1
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 2	0, 2

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
E-Cigarette	Period 2	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.6 (3.06)	0.0 (0.00)	0.7 (2.43)	0.5 (2.49)
		95% CI	-0.2, 1.3	NC, NC	-0.2, 1.6	0.0, 0.9
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 21	0, 0	0, 10	0, 21
E-Cigarette	Period 3	n(%)	79 (98.8)	39 (95.1)	31 (79.5)	149 (93.1)
		Mean (SD)	1.3 (6.80)	0.0 (0.17)	1.2 (3.03)	0.9 (5.15)
		95% CI	-0.3, 2.9	-0.1, 0.1	0.0, 2.4	0.1, 1.8
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 48	0, 1	0, 13	0, 48

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
E-Cigarette	Period 4	n(%)	76 (95.0)	36 (87.8)	30 (76.9)	142 (88.8)
		Mean (SD)	0.6 (3.03)	0.1 (0.50)	0.3 (1.47)	0.4 (2.33)
		95% CI	-0.2, 1.3	-0.1, 0.3	-0.3, 0.9	-0.1, 0.8
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 23	0, 3	0, 8	0, 23
E-Cigarette	Ambulatory	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	2.1 (7.51)	0.1 (0.48)	1.3 (3.30)	1.4 (5.69)
		95% CI	0.4, 3.8	-0.1, 0.3	0.1, 2.5	0.4, 2.4
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 48	0, 3	0, 13	0, 48

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Gums	Period 2	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.2 (0.77)	0.0 (0.37)
		95% CI	NC, NC	NC, NC	-0.1, 0.5	-0.1, 0.1
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 4	0, 4
Gums	Period 3	n(%)	79 (98.8)	39 (95.1)	31 (79.5)	149 (93.1)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.1 (0.72)	0.0 (0.33)
		95% CI	NC, NC	NC, NC	-0.2, 0.4	-0.1, 0.1
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 4	0, 4

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Gums	Period 4	n(%)	76 (95.0)	36 (87.8)	30 (76.9)	142 (88.8)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.1 (0.74)	0.0 (0.34)
		95% CI	NC, NC	NC, NC	-0.2, 0.5	-0.1, 0.1
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 4	0, 4
Gums	Ambulatory	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.2 (0.77)	0.0 (0.37)
		95% CI	NC, NC	NC, NC	-0.1, 0.5	-0.1, 0.1
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 4	0, 4

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Inhaler	Period 2	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.3 (1.75)	0.1 (0.81)
		95% CI	NC, NC	NC, NC	-0.4, 1.0	-0.1, 0.2
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 10	0, 10
Inhaler	Period 3	n(%)	79 (98.8)	39 (95.1)	31 (79.5)	149 (93.1)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.7 (2.29)	0.1 (1.07)
		95% CI	NC, NC	NC, NC	-0.2, 1.6	-0.1, 0.4
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 11	0, 11

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Inhaler	Period 4	n(%)	76 (95.0)	36 (87.8)	30 (76.9)	142 (88.8)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.8 (2.61)	0.2 (1.23)
		95% CI	NC, NC	NC, NC	-0.2, 1.8	-0.1, 0.4
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 12	0, 12
Inhaler	Ambulatory	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.7 (2.50)	0.2 (1.19)
		95% CI	NC, NC	NC, NC	-0.2, 1.7	-0.1, 0.4
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 12	0, 12

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Lozenges	Period 2	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.2 (0.77)	0.0 (0.37)
		95% CI	NC, NC	NC, NC	-0.1, 0.5	-0.1, 0.1
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 4	0, 4
Lozenges	Period 3	n(%)	79 (98.8)	39 (95.1)	31 (79.5)	149 (93.1)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.1 (0.36)	0.0 (0.17)
		95% CI	NC, NC	NC, NC	-0.1, 0.2	-0.1, 0.1
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 2	0, 2

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Lozenges	Period 4	n(%)	76 (95.0)	36 (87.8)	30 (76.9)	142 (88.8)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.1 (0.37)	0.0 (0.17)
		95% CI	NC, NC	NC, NC	-0.1, 0.3	-0.1, 0.1
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 2	0, 2
Lozenges	Ambulatory	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.2 (0.77)	0.0 (0.37)
		95% CI	NC, NC	NC, NC	-0.1, 0.5	-0.1, 0.1
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 4	0, 4

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Nasal Spray	Period 2	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0
Nasal Spray	Period 3	n(%)	79 (98.8)	39 (95.1)	31 (79.5)	149 (93.1)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Nasal Spray	Period 4	n(%)	76 (95.0)	36 (87.8)	30 (76.9)	142 (88.8)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0
Nasal Spray	Ambulatory	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Other NRT	Period 2	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0
Other NRT	Period 3	n(%)	79 (98.8)	39 (95.1)	31 (79.5)	149 (93.1)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Other NRT	Period 4	n(%)	76 (95.0)	36 (87.8)	30 (76.9)	142 (88.8)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0
Other NRT	Ambulatory	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Patches	Period 2	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.1 (0.55)	0.0 (0.26)
		95% CI	NC, NC	NC, NC	-0.1, 0.4	-0.1, 0.1
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 3	0, 3
Patches	Period 3	n(%)	79 (98.8)	39 (95.1)	31 (79.5)	149 (93.1)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.2 (0.77)	0.1 (0.36)
		95% CI	NC, NC	NC, NC	-0.1, 0.6	-0.1, 0.2
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 3	0, 3

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Patches	Period 4	n(%)	76 (95.0)	36 (87.8)	30 (76.9)	142 (88.8)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.5 (2.39)	0.1 (1.11)
		95% CI	NC, NC	NC, NC	-0.4, 1.5	-0.1, 0.3
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 13	0, 13
Patches	Ambulatory	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.6 (2.32)	0.1 (1.10)
		95% CI	NC, NC	NC, NC	-0.3, 1.4	-0.1, 0.3
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 13	0, 13

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Pipes	Period 2	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0
Pipes	Period 3	n(%)	79 (98.8)	39 (95.1)	31 (79.5)	149 (93.1)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Pipes	Period 4	n(%)	76 (95.0)	36 (87.8)	30 (76.9)	142 (88.8)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0
Pipes	Ambulatory	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Tob. Not Listed	Period 2	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.1 (1.01)	0.0 (0.00)	0.4 (1.57)	0.2 (1.04)
		95% CI	-0.2, 0.4	NC, NC	-0.2, 1.0	-0.1, 0.4
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 9	0, 0	0, 8	0, 9
Tob. Not Listed	Period 3	n(%)	79 (98.8)	39 (95.1)	31 (79.5)	149 (93.1)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.2 Summary of Maximum Daily Product Use in Ambulatory Period- FAS**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall FAS (N=160)
Tob. Not Listed	Period 4	n(%)	76 (95.0)	36 (87.8)	30 (76.9)	142 (88.8)
		Mean (SD)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 0	0, 0	0, 0	0, 0
Tob. Not Listed	Ambulatory	n(%)	80 (100)	40 (97.6)	33 (84.6)	153 (95.6)
		Mean (SD)	0.1 (1.01)	0.0 (0.00)	0.4 (1.57)	0.2 (1.04)
		95% CI	-0.2, 0.4	NC, NC	-0.2, 1.0	-0.1, 0.4
		Median	0.0	0.0	0.0	0.0
		Min, Max	0, 9	0, 0	0, 8	0, 9

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
THSm 2.2 Sticks	Period 2	n(%)	78 (97.5)	0	0
		Mean (SD)	11.68 (7.103)		
		95% CI	10.07, 13.29		
		Median	10.19		
		Min, Max	0.1, 35.8		
THSm 2.2 Sticks	Period 3	n(%)	77 (96.3)	0	0
		Mean (SD)	12.90 (9.090)		
		95% CI	10.83, 14.97		
		Median	11.60		
		Min, Max	0.0, 58.0		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
THSm 2.2 Sticks	Period 4	n(%)	74 (92.5)	0	0
		Mean (SD)	12.02 (7.195)		
		95% CI	10.35, 13.69		
		Median	11.19		
		Min, Max	0.0, 30.2		
THSm 2.2 Sticks	Ambulatory	n(%)	78 (97.5)	0	0
		Mean (SD)	12.32 (7.672)		
		95% CI	10.58, 14.05		
		Median	11.11		
		Min, Max	0.1, 38.5		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
mCC/CC	Period 2	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	1.17 (2.089)	14.96 (5.510)	1.13 (2.189)
		95% CI	0.70, 1.65	13.19, 16.73	0.34, 1.93
		Median	0.02	14.94	0.19
		Min, Max	0.0, 10.1	2.9, 31.0	0.0, 10.2
mCC/CC	Period 3	n(%)	77 (96.3)	36 (87.8)	31 (79.5)
		Mean (SD)	1.21 (2.351)	15.51 (5.802)	2.06 (3.398)
		95% CI	0.67, 1.75	13.54, 17.48	0.81, 3.32
		Median	0.00	14.63	0.20
		Min, Max	0.0, 9.9	2.7, 29.6	0.0, 12.3

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
mCC/CC	Period 4	n(%)	74 (92.5)	35 (85.4)	30 (76.9)
		Mean (SD)	1.09 (2.402)	15.79 (5.562)	1.89 (3.040)
		95% CI	0.53, 1.66	13.87, 17.70	0.75, 3.03
		Median	0.00	14.93	0.39
		Min, Max	0.0, 12.8	8.6, 32.4	0.0, 11.5
mCC/CC	Ambulatory	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	1.19 (2.121)	16.35 (8.013)	1.66 (2.699)
		95% CI	0.71, 1.67	13.79, 18.92	0.68, 2.64
		Median	0.05	14.64	0.46
		Min, Max	0.0, 8.5	3.0, 44.5	0.0, 11.4

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Chew/Smokeless Tob.	Period 2	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Chew/Smokeless Tob.	Period 3	n(%)	77 (96.3)	36 (87.8)	31 (79.5)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Chew/Smokeless Tob.	Period 4	n(%)	74 (92.5)	35 (85.4)	30 (76.9)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Chew/Smokeless Tob.	Ambulatory	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cigar/Cigarillo	Period 2	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Cigar/Cigarillo	Period 3	n(%)	77 (96.3)	36 (87.8)	31 (79.5)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cigar/Cigarillo	Period 4	n(%)	74 (92.5)	35 (85.4)	30 (76.9)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.019)
		95% CI	NC, NC	NC, NC	-0.01, 0.02
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.1
Cigar/Cigarillo	Ambulatory	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.007)
		95% CI	NC, NC	NC, NC	-0.01, 0.01
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
E-Cigarette	Period 2	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.14 (1.199)	0.00 (0.000)	0.34 (1.097)
		95% CI	-0.13, 0.42	NC, NC	-0.06, 0.74
		Median	0.00	0.00	0.00
		Min, Max	0.0, 10.6	0.0, 0.0	0.0, 4.1
E-Cigarette	Period 3	n(%)	77 (96.3)	36 (87.8)	31 (79.5)
		Mean (SD)	0.05 (0.237)	0.00 (0.006)	0.31 (0.925)
		95% CI	-0.01, 0.10	-0.01, 0.01	-0.03, 0.65
		Median	0.00	0.00	0.00
		Min, Max	0.0, 1.6	0.0, 0.0	0.0, 3.7

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
E-Cigarette	Period 4	n(%)	74 (92.5)	35 (85.4)	30 (76.9)
		Mean (SD)	0.06 (0.333)	0.00 (0.018)	0.01 (0.051)
		95% CI	-0.02, 0.14	-0.01, 0.01	-0.01, 0.03
		Median	0.00	0.00	0.00
		Min, Max	0.0, 2.4	0.0, 0.1	0.0, 0.3
E-Cigarette	Ambulatory	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.09 (0.426)	0.00 (0.008)	0.21 (0.655)
		95% CI	-0.01, 0.19	-0.01, 0.01	-0.03, 0.45
		Median	0.00	0.00	0.00
		Min, Max	0.0, 3.5	0.0, 0.0	0.0, 2.4

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Gums	Period 2	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.01 (0.031)
		95% CI	NC, NC	NC, NC	-0.01, 0.02
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.2
Gums	Period 3	n(%)	77 (96.3)	36 (87.8)	31 (79.5)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.03 (0.192)
		95% CI	NC, NC	NC, NC	-0.04, 0.11
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 1.1

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Gums	Period 4	n(%)	74 (92.5)	35 (85.4)	30 (76.9)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.05 (0.271)
		95% CI	NC, NC	NC, NC	-0.06, 0.16
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 1.5
Gums	Ambulatory	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.03 (0.165)
		95% CI	NC, NC	NC, NC	-0.03, 0.09
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.9

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Inhaler	Period 2	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.08 (0.436)
		95% CI	NC, NC	NC, NC	-0.08, 0.24
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 2.5
Inhaler	Period 3	n(%)	77 (96.3)	36 (87.8)	31 (79.5)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.29 (1.422)
		95% CI	NC, NC	NC, NC	-0.24, 0.81
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 7.9

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Inhaler	Period 4	n(%)	74 (92.5)	35 (85.4)	30 (76.9)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.54 (1.837)
		95% CI	NC, NC	NC, NC	-0.15, 1.23
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 8.7
Inhaler	Ambulatory	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.30 (1.196)
		95% CI	NC, NC	NC, NC	-0.14, 0.73
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 6.5

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Lozenges	Period 2	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.04 (0.184)
		95% CI	NC, NC	NC, NC	-0.03, 0.11
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 1.0
Lozenges	Period 3	n(%)	77 (96.3)	36 (87.8)	31 (79.5)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.01 (0.078)
		95% CI	NC, NC	NC, NC	-0.02, 0.05
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.4

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Lozenges	Period 4	n(%)	74 (92.5)	35 (85.4)	30 (76.9)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.01 (0.070)
		95% CI	NC, NC	NC, NC	-0.02, 0.04
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.4
Lozenges	Ambulatory	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.02 (0.090)
		95% CI	NC, NC	NC, NC	-0.01, 0.06
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.4

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nasal Spray	Period 2	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Nasal Spray	Period 3	n(%)	77 (96.3)	36 (87.8)	31 (79.5)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nasal Spray	Period 4	n(%)	74 (92.5)	35 (85.4)	30 (76.9)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Nasal Spray	Ambulatory	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Other NRT	Period 2	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Other NRT	Period 3	n(%)	77 (96.3)	36 (87.8)	31 (79.5)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Other NRT	Period 4	n(%)	74 (92.5)	35 (85.4)	30 (76.9)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Other NRT	Ambulatory	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Patches	Period 2	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.04 (0.169)
		95% CI	NC, NC	NC, NC	-0.02, 0.11
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.8
Patches	Period 3	n(%)	77 (96.3)	36 (87.8)	31 (79.5)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.09 (0.302)
		95% CI	NC, NC	NC, NC	-0.03, 0.20
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 1.4

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Patches	Period 4	n(%)	74 (92.5)	35 (85.4)	30 (76.9)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.09 (0.287)
		95% CI	NC, NC	NC, NC	-0.02, 0.20
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 1.2
Patches	Ambulatory	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.07 (0.215)
		95% CI	NC, NC	NC, NC	-0.01, 0.15
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.8

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Pipes	Period 2	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Pipes	Period 3	n(%)	77 (96.3)	36 (87.8)	31 (79.5)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Pipes	Period 4	n(%)	74 (92.5)	35 (85.4)	30 (76.9)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Pipes	Ambulatory	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Tob. Not Listed	Period 2	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.01 (0.079)	0.00 (0.000)	0.06 (0.266)
		95% CI	-0.01, 0.03	NC, NC	-0.04, 0.16
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.7	0.0, 0.0	0.0, 1.5
Tob. Not Listed	Period 3	n(%)	77 (96.3)	36 (87.8)	31 (79.5)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.1 Summary of Average Daily Product Use in Ambulatory Period- Safety Population**

Product	Product Use Time Periods	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Tob. Not Listed	Period 4	n(%)	74 (92.5)	35 (85.4)	30 (76.9)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Tob. Not Listed	Ambulatory	n(%)	78 (97.5)	40 (97.6)	32 (82.1)
		Mean (SD)	0.00 (0.024)	0.00 (0.000)	0.02 (0.082)
		95% CI	-0.01, 0.01	NC, NC	-0.02, 0.05
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.2	0.0, 0.0	0.0, 0.5

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
THSm 2.2 Sticks	Period 2	N	40	34	13
		n(%)	39 (97.5)	0	0
		Mean (SD)	14.73 (6.068)		
		95% CI	12.76, 16.70		
		Median	14.42		
		Min, Max	3.1, 35.5		
THSm 2.2 Sticks	Period 3	N	39	35	12
		n(%)	39 (100)	0	0
		Mean (SD)	15.18 (6.950)		
		95% CI	12.92, 17.44		
		Median	15.59		
		Min, Max	0.0, 33.5		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
THSm 2.2 Sticks	Period 4	N	47	32	9
		n(%)	47 (100)	0	0
		Mean (SD)	14.21 (7.027)		
		95% CI	12.14, 16.27		
		Median	14.38		
		Min, Max	0.0, 30.2		
mCC/CC	Period 2	N	40	34	13
		n(%)	39 (97.5)	34 (100)	13 (100)
		Mean (SD)	0.01 (0.041)	14.91 (5.854)	0.01 (0.030)
		95% CI	-0.01, 0.03	12.86, 16.96	-0.01, 0.04
		Median	0.00	14.94	0.00
		Min, Max	0.0, 0.2	2.9, 31.0	0.0, 0.1

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
mCC/CC	Period 3	N	39	35	12
		n(%)	39 (100)	32 (91.4)	12 (100)
		Mean (SD)	0.01 (0.067)	15.36 (6.124)	0.02 (0.050)
		95% CI	-0.01, 0.04	13.14, 17.57	-0.02, 0.06
		Median	0.00	14.32	0.00
		Min, Max	0.0, 0.4	2.7, 29.6	0.0, 0.2
mCC/CC	Period 4	N	47	32	9
		n(%)	47 (100)	31 (96.9)	9 (100)
		Mean (SD)	0.01 (0.056)	15.50 (5.840)	0.02 (0.057)
		95% CI	-0.01, 0.03	13.36, 17.65	-0.03, 0.07
		Median	0.00	14.34	0.00
		Min, Max	0.0, 0.4	8.6, 32.4	0.0, 0.2

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
Chew/Smokeless Tob.	Period 2	N	40	34	13
		n(%)	39 (97.5)	34 (100)	13 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Chew/Smokeless Tob.	Period 3	N	39	35	12
		n(%)	39 (100)	32 (91.4)	12 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
Chew/Smokeless Tob.	Period 4	N	47	32	9
		n(%)	47 (100)	31 (96.9)	9 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Cigar/Cigarillo	Period 2	N	40	34	13
		n(%)	39 (97.5)	34 (100)	13 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
Cigar/Cigarillo	Period 3	N	39	35	12
		n(%)	39 (100)	32 (91.4)	12 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Cigar/Cigarillo	Period 4	N	47	32	9
		n(%)	47 (100)	31 (96.9)	9 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.01 (0.034)
		95% CI	NC, NC	NC, NC	-0.02, 0.04
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.1

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
E-Cigarette	Period 2	N	40	34	13
		n(%)	39 (97.5)	34 (100)	13 (100)
		Mean (SD)	0.29 (1.694)	0.00 (0.000)	0.00 (0.000)
		95% CI	-0.27, 0.84	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 10.6	0.0, 0.0	0.0, 0.0
E-Cigarette	Period 3	N	39	35	12
		n(%)	39 (100)	32 (91.4)	12 (100)
		Mean (SD)	0.02 (0.107)	0.00 (0.006)	0.00 (0.000)
		95% CI	-0.02, 0.06	-0.01, 0.01	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.7	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
E-Cigarette	Period 4	N	47	32	9
		n(%)	47 (100)	31 (96.9)	9 (100)
		Mean (SD)	0.09 (0.416)	0.00 (0.019)	0.00 (0.000)
		95% CI	-0.04, 0.22	-0.01, 0.02	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 2.4	0.0, 0.1	0.0, 0.0
Gums	Period 2	N	40	34	13
		n(%)	39 (97.5)	34 (100)	13 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.01 (0.021)
		95% CI	NC, NC	NC, NC	-0.01, 0.02
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.1

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
Gums	Period 3	N	39	35	12
		n(%)	39 (100)	32 (91.4)	12 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Gums	Period 4	N	47	32	9
		n(%)	47 (100)	31 (96.9)	9 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
Inhaler	Period 2	N	40	34	13
		n(%)	39 (97.5)	34 (100)	13 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.19 (0.683)
		95% CI	NC, NC	NC, NC	-0.23, 0.61
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 2.5
Inhaler	Period 3	N	39	35	12
		n(%)	39 (100)	32 (91.4)	12 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.66 (2.281)
		95% CI	NC, NC	NC, NC	-0.80, 2.11
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 7.9

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
Inhaler	Period 4	N	47	32	9
		n(%)	47 (100)	31 (96.9)	9 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.96 (2.885)
		95% CI	NC, NC	NC, NC	-1.26, 3.18
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 8.7
Lozenges	Period 2	N	40	34	13
		n(%)	39 (97.5)	34 (100)	13 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.02 (0.085)
		95% CI	NC, NC	NC, NC	-0.03, 0.08
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.3

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
Lozenges	Period 3	N	39	35	12
		n(%)	39 (100)	32 (91.4)	12 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.04 (0.125)
		95% CI	NC, NC	NC, NC	-0.05, 0.12
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.4
Lozenges	Period 4	N	47	32	9
		n(%)	47 (100)	31 (96.9)	9 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.04 (0.126)
		95% CI	NC, NC	NC, NC	-0.06, 0.14
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.4

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
Nasal Spray	Period 2	N	40	34	13
		n(%)	39 (97.5)	34 (100)	13 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Nasal Spray	Period 3	N	39	35	12
		n(%)	39 (100)	32 (91.4)	12 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
Nasal Spray	Period 4	N	47	32	9
		n(%)	47 (100)	31 (96.9)	9 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Other NRT	Period 2	N	40	34	13
		n(%)	39 (97.5)	34 (100)	13 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
Other NRT	Period 3	N	39	35	12
		n(%)	39 (100)	32 (91.4)	12 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Other NRT	Period 4	N	47	32	9
		n(%)	47 (100)	31 (96.9)	9 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
Patches	Period 2	N	40	34	13
		n(%)	39 (97.5)	34 (100)	13 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.10 (0.258)
		95% CI	NC, NC	NC, NC	-0.06, 0.26
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.8
Patches	Period 3	N	39	35	12
		n(%)	39 (100)	32 (91.4)	12 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.03 (0.106)
		95% CI	NC, NC	NC, NC	-0.04, 0.10
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.4

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
Patches	Period 4	N	47	32	9
		n(%)	47 (100)	31 (96.9)	9 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Pipes	Period 2	N	40	34	13
		n(%)	39 (97.5)	34 (100)	13 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
Pipes	Period 3	N	39	35	12
		n(%)	39 (100)	32 (91.4)	12 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0
Pipes	Period 4	N	47	32	9
		n(%)	47 (100)	31 (96.9)	9 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
Tob. Not Listed	Period 2	N	40	34	13
		n(%)	39 (97.5)	34 (100)	13 (100)
		Mean (SD)	0.02 (0.111)	0.00 (0.000)	0.02 (0.055)
		95% CI	-0.02, 0.06	NC, NC	-0.02, 0.06
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.7	0.0, 0.0	0.0, 0.2
Tob. Not Listed	Period 3	N	39	35	12
		n(%)	39 (100)	32 (91.4)	12 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.3.2 Summary of Average Daily Product Use in Ambulatory Period- PP Set**

Product	Product Use Time Periods	Statistic	THSm2.2	mCC	SA
Tob. Not Listed	Period 4	N	47	32	9
		n(%)	47 (100)	31 (96.9)	9 (100)
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 (Day 6 ambulatory - Day 30 Visit), Period 3 (Day 30 Visit - Day 60 Visit) and Period 4 (Day 60 Visit - Day 90 Visit).

Note: Percentages are based on the number of subjects indicated in each product use period (N).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

**Table 15.2.2.4 Summary of Product Use by Product Use Category in Ambulatory Period - FAS**

Product Use Categorization	Period 2 n(%)	Period 3 n(%)	Period 4 n(%)	Ambulatory n(%)	Ambulatory Safety n(%)
THSm2.2 Arm	80	80	80	80	80
THSm2.2 ([70-100]%)	64(80.0)	60(75.0)	58(72.5)	63(78.8)	67(83.8)
Primarily THSm2.2 ([95-100]%)	47(58.8)	47(58.8)	51(63.8)	46(57.5)	53(66.3)
Exclusively THSm2.2 (100%)	34(42.5)	38(47.5)	44(55.0)	27(33.8)	32(40.0)
Predominantly THSm2.2 ([70-95]%)	17(21.3)	13(16.3)	7(8.8)	17(21.3)	14(17.5)
Dual ([30-70]%)	11(13.8)	12(15.0)	12(15.0)	10(12.5)	10(12.5)
Dual mostly THSm2.2 ([60-70]%)	3(3.8)	2(2.5)	3(3.8)	1(1.3)	2(2.5)
Dual balanced ([40-60]%)	7(8.8)	6(7.5)	5(6.3)	7(8.8)	6(7.5)
Dual mostly CC ([30-40]%)	1(1.3)	4(5.0)	4(5.0)	2(2.5)	2(2.5)
CC ([0-30]%)	5(6.3)	6(7.5)	5(6.3)	3(3.8)	3(3.8)
Predominantly CC ([5-30]%)	4(5.0)	5(6.3)	2(2.5)	2(2.5)	2(2.5)
Primarily CC ([0-5]%)	1(1.3)	1(1.3)	3(3.8)	1(1.3)	1(1.3)
Exclusively CC (0%)	0	0	2(2.5)	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Ambulatory Safety column refers to product use categorization over the whole ambulatory period based on missing imputation rules for safety summaries.

Note: Percentages are based on the number of subjects indicated in each study arm for the FAS.

Note: Product use categories in first 4 columns calculated using imputation rules. Product use category in last column calculated without using imputation.

Note: N/A = Not applicable.

**Table 15.2.2.4 Summary of Product Use by Product Use Category in Ambulatory Period - FAS**

Product Use Categorization	Period 2 n(%)	Period 3 n(%)	Period 4 n(%)	Ambulatory n(%)	Ambulatory Safety n(%)
Abstinent	0	0	1(1.3)	0	0
Predominantly Abstinent	0	0	0	0	0
Not Abstinent	0	1(1.3)	0	0	0
Discontinued in previous period	0	1(1.3)	4(5.0)	4(5.0)	N/A
Missing	N/A	N/A	N/A	N/A	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Ambulatory Safety column refers to product use categorization over the whole ambulatory period based on missing imputation rules for safety summaries.

Note: Percentages are based on the number of subjects indicated in each study arm for the FAS.

Note: Product use categories in first 4 columns calculated using imputation rules. Product use category in last column calculated without using imputation.

Note: N/A = Not applicable.

**Table 15.2.2.4 Summary of Product Use by Product Use Category in Ambulatory Period - FAS**

Product Use Categorization	Period 2 n(%)	Period 3 n(%)	Period 4 n(%)	Ambulatory n(%)	Ambulatory Safety n(%)
mCC Arm	41	41	41	41	41
CC Only (Exclusively CC)	40(97.6)	39(95.1)	36(87.8)	36(87.8)	39(95.1)
CC Dual (Use of other products)	0	1(2.4)	1(2.4)	1(2.4)	1(2.4)
Discontinued in previous period	1(2.4)	1(2.4)	4(9.8)	4(9.8)	N/A
Missing	N/A	N/A	N/A	N/A	1(2.4)
SA Arm	39	39	39	39	39
Abstinent	8(20.5)	7(17.9)	9(23.1)	6(15.4)	6(15.4)
Predominantly Abstinent	4(10.3)	5(12.8)	2(5.1)	2(5.1)	4(10.3)
Not Abstinent	22(56.4)	21(53.8)	22(56.4)	25(64.1)	24(61.5)
Discontinued in previous period	5(12.8)	6(15.4)	6(15.4)	6(15.4)	N/A
Missing	N/A	N/A	N/A	N/A	5(12.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Ambulatory Safety column refers to product use categorization over the whole ambulatory period based on missing imputation rules for safety summaries.

Note: Percentages are based on the number of subjects indicated in each study arm for the FAS.

Note: Product use categories in first 4 columns calculated using imputation rules. Product use category in last column calculated without using imputation.

Note: N/A = Not applicable.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
THSm2.2	Period 2	n	63	10	5	0	0	78
		Mean (SD)	13.45 (6.660)	5.58 (2.248)	1.56 (1.387)			11.68 (7.103)
		95% CI	11.77, 15.13	3.97, 7.20	-0.17, 3.29			10.07, 13.29
		Median	12.35	5.65	1.19			10.19
		Min, Max	1.2, 35.8	1.5, 8.7	0.1, 3.8			0.1, 35.8
	Period 3	n	60	11	5	1	0	77
		Mean (SD)	15.44 (8.515)	5.73 (3.865)	0.79 (0.523)	NC		12.90 (9.090)
		95% CI	13.23, 17.64	3.13, 8.33	0.14, 1.45	NC		10.83, 14.97
		Median	13.53	6.40	0.89	NC		11.60
		Min, Max	3.9, 58.0	0.4, 13.7	0.1, 1.5	NC		0.0, 58.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
THSm2.2	Period 4	n	58	10	5	0	1	74
		Mean (SD)	14.13 (6.361)	6.83 (3.578)	0.33 (0.547)		NC	12.02 (7.195)
		95% CI	12.45, 15.81	4.27, 9.40	-0.36, 1.01		NC	10.35, 13.69
		Median	14.22	5.93	0.04		NC	11.19
		Min, Max	0.7, 30.2	2.3, 15.2	0.0, 1.3		NC	0.0, 30.2
	Overall	n	63	10	3	0	0	76
		Mean (SD)	14.16 (7.275)	5.96 (2.785)	NC			12.56 (7.626)
		95% CI	12.33, 16.00	3.96, 7.96	NC			10.81, 14.31
		Median	13.35	6.12	NC			11.67
		Min, Max	0.9, 38.5	3.4, 12.6	NC			0.1, 38.5

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
mCC/CC	Period 2	n	63	10	5	0	0	78
		Mean (SD)	0.49 (0.907)	4.92 (2.910)	2.29 (2.838)			1.17 (2.089)
		95% CI	0.26, 0.72	2.84, 7.01	-1.23, 5.82			0.70, 1.65
		Median	0.00	5.58	1.08			0.02
		Min, Max	0.0, 4.1	0.0, 10.1	0.0, 6.5			0.0, 10.1
	Period 3	n	60	11	5	1	0	77
		Mean (SD)	0.38 (0.807)	4.32 (3.571)	4.58 (3.451)	NC		1.21 (2.351)
		95% CI	0.17, 0.59	1.92, 6.73	0.29, 8.87	NC		0.67, 1.75
		Median	0.00	5.63	3.34	NC		0.00
		Min, Max	0.0, 3.7	0.0, 8.2	1.1, 9.9	NC		0.0, 9.9

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
mCC/CC	Period 4	n	58	10	5	0	1	74
		Mean (SD)	0.21 (0.609)	4.25 (3.118)	5.26 (4.440)		NC	1.09 (2.402)
		95% CI	0.04, 0.37	2.02, 6.49	-0.25, 10.78		NC	0.53, 1.66
		Median	0.00	4.42	4.55		NC	0.00
		Min, Max	0.0, 2.9	0.0, 8.6	1.2, 12.8		NC	0.0, 12.8
	Overall	n	63	10	3	0	0	76
		Mean (SD)	0.42 (0.806)	5.18 (2.957)	NC			1.19 (2.140)
		95% CI	0.21, 0.63	3.06, 7.30	NC			0.70, 1.68
		Median	0.00	6.12	NC			0.05
		Min, Max	0.0, 3.4	0.0, 8.5	NC			0.0, 8.5

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Chew/Smokeless Tob.	Period 2	n	63	10	5	0	0	78
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC			NC, NC
		Median	0.00	0.00	0.00			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0			0.0, 0.0
	Period 3	n	60	11	5	1	0	77
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC		NC, NC
		Median	0.00	0.00	0.00	NC		0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Chew/Smokeless Tob.	Period 4	n	58	10	5	0	1	74
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)		NC	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC		NC	NC, NC
		Median	0.00	0.00	0.00		NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0		NC	0.0, 0.0
	Overall	n	63	10	3	0	0	76
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC			NC, NC
		Median	0.00	0.00	NC			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC			0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Cigar/Cigarillo	Period 2	n	63	10	5	0	0	78
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC			NC, NC
		Median	0.00	0.00	0.00			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0			0.0, 0.0
	Period 3	n	60	11	5	1	0	77
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC		NC, NC
		Median	0.00	0.00	0.00	NC		0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Cigar/Cigarillo	Period 4	n	58	10	5	0	1	74
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)		NC	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC		NC	NC, NC
		Median	0.00	0.00	0.00		NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0		NC	0.0, 0.0
	Overall	n	63	10	3	0	0	76
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC			NC, NC
		Median	0.00	0.00	NC			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC			0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
E-Cigarette	Period 2	n	63	10	5	0	0	78
		Mean (SD)	0.18 (1.334)	0.01 (0.038)	0.00 (0.000)			0.14 (1.199)
		95% CI	-0.16, 0.52	-0.02, 0.04	NC, NC			-0.13, 0.42
		Median	0.00	0.00	0.00			0.00
		Min, Max	0.0, 10.6	0.0, 0.1	0.0, 0.0			0.0, 10.6
	Period 3	n	60	11	5	1	0	77
		Mean (SD)	0.03 (0.207)	0.01 (0.021)	0.24 (0.532)	NC		0.05 (0.237)
		95% CI	-0.03, 0.09	-0.01, 0.02	-0.43, 0.90	NC		-0.01, 0.10
		Median	0.00	0.00	0.00	NC		0.00
		Min, Max	0.0, 1.6	0.0, 0.1	0.0, 1.2	NC		0.0, 1.6

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
E-Cigarette	Period 4	n	58	10	5	0	1	74
		Mean (SD)	0.07 (0.375)	0.00 (0.000)	0.00 (0.000)		NC	0.06 (0.333)
		95% CI	-0.03, 0.18	NC, NC	NC, NC		NC	-0.02, 0.14
		Median	0.00	0.00	0.00		NC	0.00
		Min, Max	0.0, 2.4	0.0, 0.0	0.0, 0.0		NC	0.0, 2.4
	Overall	n	63	10	3	0	0	76
		Mean (SD)	0.10 (0.463)	0.01 (0.038)	NC			0.08 (0.422)
		95% CI	-0.03, 0.22	-0.02, 0.04	NC			-0.02, 0.18
		Median	0.00	0.00	NC			0.00
		Min, Max	0.0, 3.5	0.0, 0.1	NC			0.0, 3.5

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Gums	Period 2	n	63	10	5	0	0	78
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC			NC, NC
		Median	0.00	0.00	0.00			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0			0.0, 0.0
	Period 3	n	60	11	5	1	0	77
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC		NC, NC
		Median	0.00	0.00	0.00	NC		0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Gums	Period 4	n	58	10	5	0	1	74
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)		NC	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC		NC	NC, NC
		Median	0.00	0.00	0.00		NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0		NC	0.0, 0.0
	Overall	n	63	10	3	0	0	76
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC			NC, NC
		Median	0.00	0.00	NC			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC			0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Inhaler	Period 2	n	63	10	5	0	0	78
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC			NC, NC
		Median	0.00	0.00	0.00			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0			0.0, 0.0
	Period 3	n	60	11	5	1	0	77
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC		NC, NC
		Median	0.00	0.00	0.00	NC		0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

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**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Inhaler	Period 4	n	58	10	5	0	1	74
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)		NC	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC		NC	NC, NC
		Median	0.00	0.00	0.00		NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0		NC	0.0, 0.0
	Overall	n	63	10	3	0	0	76
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC			NC, NC
		Median	0.00	0.00	NC			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC			0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

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**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Lozenges	Period 2	n	63	10	5	0	0	78
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC			NC, NC
		Median	0.00	0.00	0.00			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0			0.0, 0.0
	Period 3	n	60	11	5	1	0	77
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC		NC, NC
		Median	0.00	0.00	0.00	NC		0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

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Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Lozenges	Period 4	n	58	10	5	0	1	74
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)		NC	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC		NC	NC, NC
		Median	0.00	0.00	0.00		NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0		NC	0.0, 0.0
	Overall	n	63	10	3	0	0	76
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC			NC, NC
		Median	0.00	0.00	NC			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC			0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

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Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Nasal Spray	Period 2	n	63	10	5	0	0	78
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC			NC, NC
		Median	0.00	0.00	0.00			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0			0.0, 0.0
	Period 3	n	60	11	5	1	0	77
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC		NC, NC
		Median	0.00	0.00	0.00	NC		0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

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Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Nasal Spray	Period 4	n	58	10	5	0	1	74
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)		NC	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC		NC	NC, NC
		Median	0.00	0.00	0.00		NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0		NC	0.0, 0.0
	Overall	n	63	10	3	0	0	76
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC			NC, NC
		Median	0.00	0.00	NC			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC			0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

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**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Other NRT	Period 2	n	63	10	5	0	0	78
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC			NC, NC
		Median	0.00	0.00	0.00			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0			0.0, 0.0
	Period 3	n	60	11	5	1	0	77
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC		NC, NC
		Median	0.00	0.00	0.00	NC		0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

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			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Other NRT	Period 4	n	58	10	5	0	1	74
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)		NC	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC		NC	NC, NC
		Median	0.00	0.00	0.00		NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0		NC	0.0, 0.0
	Overall	n	63	10	3	0	0	76
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC			NC, NC
		Median	0.00	0.00	NC			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC			0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

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Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Patches	Period 2	n	63	10	5	0	0	78
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC			NC, NC
		Median	0.00	0.00	0.00			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0			0.0, 0.0
	Period 3	n	60	11	5	1	0	77
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC		NC, NC
		Median	0.00	0.00	0.00	NC		0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

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			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Patches	Period 4	n	58	10	5	0	1	74
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)		NC	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC		NC	NC, NC
		Median	0.00	0.00	0.00		NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0		NC	0.0, 0.0
	Overall	n	63	10	3	0	0	76
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC			NC, NC
		Median	0.00	0.00	NC			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC			0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

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Note: Tob. Not Listed refers to other tobacco products not previously listed.

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Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Pipes	Period 2	n	63	10	5	0	0	78
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC			NC, NC
		Median	0.00	0.00	0.00			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0			0.0, 0.0
	Period 3	n	60	11	5	1	0	77
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC		NC, NC
		Median	0.00	0.00	0.00	NC		0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

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			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Pipes	Period 4	n	58	10	5	0	1	74
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)		NC	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC		NC	NC, NC
		Median	0.00	0.00	0.00		NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0		NC	0.0, 0.0
	Overall	n	63	10	3	0	0	76
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC			0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC			NC, NC
		Median	0.00	0.00	NC			0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC			0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

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Note: Tob. Not Listed refers to other tobacco products not previously listed.

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Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2 (N=80)
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Tob. Not Listed	Period 2	n	63	10	5	0	0	78
		Mean (SD)	0.01 (0.088)	0.00 (0.000)	0.00 (0.000)			0.01 (0.079)
		95% CI	-0.02, 0.04	NC, NC	NC, NC			-0.01, 0.03
		Median	0.00	0.00	0.00			0.00
		Min, Max	0.0, 0.7	0.0, 0.0	0.0, 0.0			0.0, 0.7
	Period 3	n	60	11	5	1	0	77
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC		NC, NC
		Median	0.00	0.00	0.00	NC		0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

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			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Tob. Not Listed	Period 4	n	58	10	5	0	1	74
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)		NC	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC		NC	NC, NC
		Median	0.00	0.00	0.00		NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0		NC	0.0, 0.0
	Overall	n	63	10	3	0	0	76
		Mean (SD)	0.00 (0.000)	0.02 (0.067)	NC			0.00 (0.025)
		95% CI	NC, NC	-0.03, 0.07	NC			-0.01, 0.01
		Median	0.00	0.00	NC			0.00
		Min, Max	0.0, 0.0	0.0, 0.2	NC			0.0, 0.2

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
THSm2.2	Period 2	n	46	33	17	63
		Mean (SD)	14.93 (6.575)	14.14 (4.596)	9.44 (5.184)	13.45 (6.660)
		95% CI	12.98, 16.89	12.51, 15.78	6.77, 12.11	11.77, 15.13
		Median	14.08	13.70	8.27	12.35
		Min, Max	3.1, 35.8	6.1, 25.9	1.2, 21.7	1.2, 35.8
	Period 3	n	47	38	13	60
		Mean (SD)	17.15 (8.726)	15.70 (6.124)	9.23 (3.376)	15.44 (8.515)
		95% CI	14.59, 19.72	13.68, 17.72	7.19, 11.28	13.23, 17.64
		Median	16.10	14.93	9.27	13.53
		Min, Max	3.9, 58.0	3.9, 33.5	4.0, 13.9	3.9, 58.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Appendix 15.3.2.1.3

Study ID:ZRHM-REXA-08-US Program:t_avg_prduse_cat_fas.sas Status: Final

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**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
THSm2.2	Period 4	n	51	44	7	58
		Mean (SD)	14.46 (6.486)	14.96 (6.544)	11.71 (5.099)	14.13 (6.361)
		95% CI	12.63, 16.29	12.97, 16.96	6.99, 16.43	12.45, 15.81
		Median	14.38	16.45	11.03	14.22
		Min, Max	0.7, 30.2	0.7, 30.2	4.9, 17.4	0.7, 30.2
	Overall	n	46	27	17	63
		Mean (SD)	15.32 (6.644)	14.99 (4.579)	11.04 (8.171)	14.16 (7.275)
		95% CI	13.34, 17.29	13.18, 16.81	6.84, 15.25	12.33, 16.00
		Median	15.57	15.01	9.48	13.35
		Min, Max	2.1, 34.9	7.5, 24.2	0.9, 38.5	0.9, 38.5

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
mCC/CC	Period 2	n	46	33	17	63
		Mean (SD)	0.06 (0.173)	0.00 (0.000)	1.64 (1.078)	0.49 (0.907)
		95% CI	0.01, 0.12	NC, NC	1.08, 2.20	0.26, 0.72
		Median	0.00	0.00	1.31	0.00
		Min, Max	0.0, 0.8	0.0, 0.0	0.3, 4.1	0.0, 4.1
	Period 3	n	47	38	13	60
		Mean (SD)	0.06 (0.138)	0.00 (0.000)	1.55 (1.111)	0.38 (0.807)
		95% CI	0.01, 0.10	NC, NC	0.88, 2.23	0.17, 0.59
		Median	0.00	0.00	1.23	0.00
		Min, Max	0.0, 0.7	0.0, 0.0	0.0, 3.7	0.0, 3.7

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
mCC/CC	Period 4	n	51	44	7	58
		Mean (SD)	0.03 (0.108)	0.00 (0.000)	1.55 (1.022)	0.21 (0.609)
		95% CI	-0.01, 0.06	NC, NC	0.60, 2.50	0.04, 0.37
		Median	0.00	0.00	1.17	0.00
		Min, Max	0.0, 0.7	0.0, 0.0	0.5, 2.9	0.0, 2.9
	Overall	n	46	27	17	63
		Mean (SD)	0.09 (0.293)	0.00 (0.000)	1.31 (1.063)	0.42 (0.806)
		95% CI	0.00, 0.19	NC, NC	0.76, 1.86	0.21, 0.63
		Median	0.00	0.00	1.01	0.00
		Min, Max	0.0, 1.8	0.0, 0.0	0.0, 3.4	0.0, 3.4

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Chew/Smokeless Tob.	Period 2	n	46	33	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Period 3	n	47	38	13	60
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Appendix 15.3.2.1.3

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**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Chew/Smokeless Tob.	Period 4	n	51	44	7	58
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Overall	n	46	27	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Appendix 15.3.2.1.3

Study ID:ZRHM-REXA-08-US Program:t_avg_prduse_cat_fas.sas Status: Final

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**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Cigar/Cigarillo	Period 2	n	46	33	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Period 3	n	47	38	13	60
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Appendix 15.3.2.1.3

Study ID:ZRHM-REXA-08-US Program:t_avg_prduse_cat_fas.sas Status: Final

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**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Cigar/Cigarillo	Period 4	n	51	44	7	58
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Overall	n	46	27	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
E-Cigarette	Period 2	n	46	33	17	63
		Mean (SD)	0.24 (1.560)	0.00 (0.000)	0.00 (0.000)	0.18 (1.334)
		95% CI	-0.23, 0.71	NC, NC	NC, NC	-0.16, 0.52
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 10.6	0.0, 0.0	0.0, 0.0	0.0, 10.6
	Period 3	n	47	38	13	60
		Mean (SD)	0.03 (0.234)	0.00 (0.000)	0.00 (0.000)	0.03 (0.207)
		95% CI	-0.04, 0.11	NC, NC	NC, NC	-0.03, 0.09
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 1.6	0.0, 0.0	0.0, 0.0	0.0, 1.6

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
E-Cigarette	Period 4	n	51	44	7	58
		Mean (SD)	0.08 (0.400)	0.00 (0.000)	0.00 (0.000)	0.07 (0.375)
		95% CI	-0.03, 0.20	NC, NC	NC, NC	-0.03, 0.18
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 2.4	0.0, 0.0	0.0, 0.0	0.0, 2.4
	Overall	n	46	27	17	63
		Mean (SD)	0.11 (0.527)	0.00 (0.000)	0.06 (0.212)	0.10 (0.463)
		95% CI	-0.05, 0.27	NC, NC	-0.05, 0.17	-0.03, 0.22
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 3.5	0.0, 0.0	0.0, 0.9	0.0, 3.5

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Gums	Period 2	n	46	33	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Period 3	n	47	38	13	60
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Gums	Period 4	n	51	44	7	58
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Overall	n	46	27	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Inhaler	Period 2	n	46	33	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Period 3	n	47	38	13	60
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Appendix 15.3.2.1.3

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**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Inhaler	Period 4	n	51	44	7	58
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Overall	n	46	27	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Lozenges	Period 2	n	46	33	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Period 3	n	47	38	13	60
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Appendix 15.3.2.1.3

Study ID:ZRHM-REXA-08-US Program:t_avg_prduse_cat_fas.sas Status: Final

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**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Lozenges	Period 4	n	51	44	7	58
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Overall	n	46	27	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Appendix 15.3.2.1.3

Study ID:ZRHM-REXA-08-US Program:t_avg_prduse_cat_fas.sas Status: Final

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**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Nasal Spray	Period 2	n	46	33	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Period 3	n	47	38	13	60
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Appendix 15.3.2.1.3

Study ID:ZRHM-REXA-08-US Program:t_avg_prduse_cat_fas.sas Status: Final

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**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Nasal Spray	Period 4	n	51	44	7	58
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Overall	n	46	27	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Other NRT	Period 2	n	46	33	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Period 3	n	47	38	13	60
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Other NRT	Period 4	n	51	44	7	58
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Overall	n	46	27	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Patches	Period 2	n	46	33	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Period 3	n	47	38	13	60
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Patches	Period 4	n	51	44	7	58
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Overall	n	46	27	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Pipes	Period 2	n	46	33	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Period 3	n	47	38	13	60
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Pipes	Period 4	n	51	44	7	58
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Overall	n	46	27	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Tob. Not Listed	Period 2	n	46	33	17	63
		Mean (SD)	0.02 (0.103)	0.00 (0.000)	0.00 (0.000)	0.01 (0.088)
		95% CI	-0.02, 0.05	NC, NC	NC, NC	-0.02, 0.04
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.7	0.0, 0.0	0.0, 0.0	0.0, 0.7
	Period 3	n	47	38	13	60
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	THSm2.2 Product Use Category			
			Primarily THSm2.2 ([70-95]%)	Exclusively THSm2.2 ([95-100]%)	Predominantly THSm2.2 (100%)	THSm2.2 ([70-100]%)
Tob. Not Listed	Period 4	n	51	44	7	58
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Overall	n	46	27	17	63
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
mCC/CC	Period 2	n	40	0	40
		Mean (SD)	14.96 (5.510)		14.96 (5.510)
		95% CI	13.19, 16.73		13.19, 16.73
		Median	14.94		14.94
		Min, Max	2.9, 31.0		2.9, 31.0
	Period 3	n	35	1	36
		Mean (SD)	15.66 (5.816)	NC	15.51 (5.802)
		95% CI	13.66, 17.66	NC	13.54, 17.48
		Median	14.77	NC	14.63
		Min, Max	2.7, 29.6	NC	2.7, 29.6

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
mCC/CC	Period 4	n	34	1	35
		Mean (SD)	15.97 (5.538)	NC	15.79 (5.562)
		95% CI	14.03, 17.91	NC	13.87, 17.70
		Median	15.12	NC	14.93
		Min, Max	8.6, 32.4	NC	8.6, 32.4
	Overall	n	36	1	37
		Mean (SD)	16.34 (7.373)	NC	16.18 (7.336)
		95% CI	13.84, 18.84	NC	13.73, 18.63
		Median	15.26	NC	14.68
		Min, Max	3.0, 44.5	NC	3.0, 44.5

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Chew/Smokeless Tob.	Period 2	n	40	0	40
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	35	1	36
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Chew/Smokeless Tob.	Period 4	n	34	1	35
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Overall	n	36	1	37
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Cigar/Cigarillo	Period 2	n	40	0	40
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	35	1	36
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Cigar/Cigarillo	Period 4	n	34	1	35
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Overall	n	36	1	37
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
E-Cigarette	Period 2	n	40	0	40
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	35	1	36
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.006)
		95% CI	NC, NC	NC	-0.01, 0.01
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
E-Cigarette	Period 4	n	34	1	35
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.018)
		95% CI	NC, NC	NC	-0.01, 0.01
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.1
	Overall	n	36	1	37
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.008)
		95% CI	NC, NC	NC	-0.01, 0.01
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Gums	Period 2	n	40	0	40
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	35	1	36
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Gums	Period 4	n	34	1	35
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Overall	n	36	1	37
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Inhaler	Period 2	n	40	0	40
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	35	1	36
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Inhaler	Period 4	n	34	1	35
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Overall	n	36	1	37
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Lozenges	Period 2	n	40	0	40
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	35	1	36
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Lozenges	Period 4	n	34	1	35
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Overall	n	36	1	37
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Nasal Spray	Period 2	n	40	0	40
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	35	1	36
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Nasal Spray	Period 4	n	34	1	35
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Overall	n	36	1	37
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Other NRT	Period 2	n	40	0	40
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	35	1	36
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Other NRT	Period 4	n	34	1	35
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Overall	n	36	1	37
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Patches	Period 2	n	40	0	40
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	35	1	36
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Patches	Period 4	n	34	1	35
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Overall	n	36	1	37
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Pipes	Period 2	n	40	0	40
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	35	1	36
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Pipes	Period 4	n	34	1	35
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Overall	n	36	1	37
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Tob. Not Listed	Period 2	n	40	0	40
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	35	1	36
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	mCC Product Use Category		mCC (N=41)
			Exclusively CC	Dual CC	
Tob. Not Listed	Period 4	n	34	1	35
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Overall	n	36	1	37
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
mCC/CC	Period 2	n	8	4	20	32
		Mean (SD)	0.00 (0.000)	0.05 (0.037)	1.80 (2.561)	1.13 (2.189)
		95% CI	NC, NC	-0.02, 0.11	0.60, 3.00	0.34, 1.93
		Median	0.00	0.06	0.71	0.19
		Min, Max	0.0, 0.0	0.0, 0.1	0.0, 10.2	0.0, 10.2
	Period 3	n	7	5	19	31
		Mean (SD)	0.00 (0.000)	0.05 (0.074)	3.35 (3.834)	2.06 (3.398)
		95% CI	NC, NC	-0.05, 0.14	1.50, 5.21	0.81, 3.32
		Median	0.00	0.00	1.53	0.20
		Min, Max	0.0, 0.0	0.0, 0.2	0.0, 12.3	0.0, 12.3

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
mCC/CC	Period 4	n	9	2	19	30
		Mean (SD)	0.00 (0.000)	NC	2.97 (3.393)	1.89 (3.040)
		95% CI	NC, NC	NC	1.33, 4.61	0.75, 3.03
		Median	0.00	NC	1.17	0.39
		Min, Max	0.0, 0.0	NC	0.0, 11.5	0.0, 11.5
	Overall	n	6	2	24	32
		Mean (SD)	0.00 (0.000)	NC	2.21 (2.927)	1.66 (2.699)
		95% CI	NC, NC	NC	0.97, 3.45	0.68, 2.64
		Median	0.00	NC	1.22	0.46
		Min, Max	0.0, 0.0	NC	0.0, 11.4	0.0, 11.4

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Chew/Smokeless Tob.	Period 2	n	8	4	20	32
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Period 3	n	7	5	19	31
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Chew/Smokeless Tob.	Period 4	n	9	2	19	30
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC	NC, NC
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0	0.0, 0.0
	Overall	n	6	2	24	32
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC	NC, NC
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Cigar/Cigarillo	Period 2	n	8	4	20	32
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Period 3	n	7	5	19	31
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Cigar/Cigarillo	Period 4	n	9	2	19	30
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)	0.00 (0.019)
		95% CI	NC, NC	NC	NC, NC	-0.01, 0.02
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0	0.0, 0.1
	Overall	n	6	2	24	32
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)	0.00 (0.007)
		95% CI	NC, NC	NC	NC, NC	-0.01, 0.01
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
E-Cigarette	Period 2	n	8	4	20	32
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.55 (1.358)	0.34 (1.097)
		95% CI	NC, NC	NC, NC	-0.09, 1.19	-0.06, 0.74
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 4.1	0.0, 4.1
	Period 3	n	7	5	19	31
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.51 (1.149)	0.31 (0.925)
		95% CI	NC, NC	NC, NC	-0.05, 1.06	-0.03, 0.65
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 3.7	0.0, 3.7

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
E-Cigarette	Period 4	n	9	2	19	30
		Mean (SD)	0.00 (0.000)	NC	0.01 (0.064)	0.01 (0.051)
		95% CI	NC, NC	NC	-0.02, 0.05	-0.01, 0.03
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.3	0.0, 0.3
	Overall	n	6	2	24	32
		Mean (SD)	0.00 (0.000)	NC	0.28 (0.746)	0.21 (0.655)
		95% CI	NC, NC	NC	-0.04, 0.60	-0.03, 0.45
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 2.4	0.0, 2.4

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Gums	Period 2	n	8	4	20	32
		Mean (SD)	0.00 (0.000)	0.02 (0.039)	0.01 (0.035)	0.01 (0.031)
		95% CI	NC, NC	-0.05, 0.09	-0.01, 0.03	-0.01, 0.02
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.1	0.0, 0.2	0.0, 0.2
	Period 3	n	7	5	19	31
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.06 (0.245)	0.03 (0.192)
		95% CI	NC, NC	NC, NC	-0.07, 0.18	-0.04, 0.11
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 1.1	0.0, 1.1

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Gums	Period 4	n	9	2	19	30
		Mean (SD)	0.00 (0.000)	NC	0.08 (0.341)	0.05 (0.271)
		95% CI	NC, NC	NC	-0.09, 0.25	-0.06, 0.16
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 1.5	0.0, 1.5
	Overall	n	6	2	24	32
		Mean (SD)	0.00 (0.000)	NC	0.04 (0.190)	0.03 (0.165)
		95% CI	NC, NC	NC	-0.05, 0.12	-0.03, 0.09
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.9	0.0, 0.9

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Inhaler	Period 2	n	8	4	20	32
		Mean (SD)	0.31 (0.871)	0.00 (0.000)	0.00 (0.000)	0.08 (0.436)
		95% CI	-0.42, 1.04	NC, NC	NC, NC	-0.08, 0.24
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 2.5	0.0, 0.0	0.0, 0.0	0.0, 2.5
	Period 3	n	7	5	19	31
		Mean (SD)	1.13 (2.986)	0.00 (0.000)	0.05 (0.201)	0.29 (1.422)
		95% CI	-1.64, 3.90	NC, NC	-0.05, 0.16	-0.24, 0.81
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 7.9	0.0, 0.0	0.0, 0.9	0.0, 7.9

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Inhaler	Period 4	n	9	2	19	30
		Mean (SD)	1.80 (3.109)	NC	0.00 (0.000)	0.54 (1.837)
		95% CI	-0.59, 4.20	NC	NC, NC	-0.15, 1.23
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 8.7	NC	0.0, 0.0	0.0, 8.7
	Overall	n	6	2	24	32
		Mean (SD)	1.08 (2.652)	NC	0.12 (0.446)	0.30 (1.196)
		95% CI	-1.70, 3.87	NC	-0.07, 0.32	-0.14, 0.73
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 6.5	NC	0.0, 2.0	0.0, 6.5

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Lozenges	Period 2	n	8	4	20	32
		Mean (SD)	0.04 (0.109)	0.00 (0.000)	0.05 (0.224)	0.04 (0.184)
		95% CI	-0.06, 0.13	NC, NC	-0.06, 0.16	-0.03, 0.11
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.3	0.0, 0.0	0.0, 1.0	0.0, 1.0
	Period 3	n	7	5	19	31
		Mean (SD)	0.06 (0.164)	0.00 (0.000)	0.00 (0.000)	0.01 (0.078)
		95% CI	-0.09, 0.22	NC, NC	NC, NC	-0.02, 0.05
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.4	0.0, 0.0	0.0, 0.0	0.0, 0.4

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Lozenges	Period 4	n	9	2	19	30
		Mean (SD)	0.04 (0.127)	NC	0.00 (0.000)	0.01 (0.070)
		95% CI	-0.06, 0.14	NC	NC, NC	-0.02, 0.04
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.4	NC	0.0, 0.0	0.0, 0.4
	Overall	n	6	2	24	32
		Mean (SD)	0.06 (0.154)	NC	0.01 (0.071)	0.02 (0.090)
		95% CI	-0.10, 0.23	NC	-0.02, 0.05	-0.01, 0.06
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.4	NC	0.0, 0.3	0.0, 0.4

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Nasal Spray	Period 2	n	8	4	20	32
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Period 3	n	7	5	19	31
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Nasal Spray	Period 4	n	9	2	19	30
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC	NC, NC
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0	0.0, 0.0
	Overall	n	6	2	24	32
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC	NC, NC
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Other NRT	Period 2	n	8	4	20	32
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Period 3	n	7	5	19	31
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Other NRT	Period 4	n	9	2	19	30
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC	NC, NC
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0	0.0, 0.0
	Overall	n	6	2	24	32
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC	NC, NC
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Patches	Period 2	n	8	4	20	32
		Mean (SD)	0.06 (0.164)	0.21 (0.424)	0.00 (0.000)	0.04 (0.169)
		95% CI	-0.08, 0.20	-0.47, 0.89	NC, NC	-0.02, 0.11
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.5	0.0, 0.8	0.0, 0.0	0.0, 0.8
	Period 3	n	7	5	19	31
		Mean (SD)	0.00 (0.000)	0.07 (0.164)	0.12 (0.376)	0.09 (0.302)
		95% CI	NC, NC	-0.14, 0.28	-0.06, 0.31	-0.03, 0.20
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.4	0.0, 1.4	0.0, 1.4

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Patches	Period 4	n	9	2	19	30
		Mean (SD)	0.00 (0.000)	NC	0.14 (0.354)	0.09 (0.287)
		95% CI	NC, NC	NC	-0.04, 0.31	-0.02, 0.20
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 1.2	0.0, 1.2
	Overall	n	6	2	24	32
		Mean (SD)	0.00 (0.000)	NC	0.10 (0.244)	0.07 (0.215)
		95% CI	NC, NC	NC	-0.01, 0.20	-0.01, 0.15
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.8	0.0, 0.8

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Pipes	Period 2	n	8	4	20	32
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0
	Period 3	n	7	5	19	31
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Pipes	Period 4	n	9	2	19	30
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC	NC, NC
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0	0.0, 0.0
	Overall	n	6	2	24	32
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC	NC, NC
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Tob. Not Listed	Period 2	n	8	4	20	32
		Mean (SD)	0.00 (0.000)	0.04 (0.077)	0.08 (0.336)	0.06 (0.266)
		95% CI	NC, NC	-0.09, 0.17	-0.08, 0.24	-0.04, 0.16
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.2	0.0, 1.5	0.0, 1.5
	Period 3	n	7	5	19	31
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC, NC	NC, NC
		Median	0.00	0.00	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	0.0, 0.0	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.1 Summary of Average Reported Daily Product Use by Product Use Category in Ambulatory Period - FAS**

Product	Period	Statistic	SA Product Use Category			SA (N=39)
			Abstinent	Predominantly Abstinent	Not Abstinent	
Tob. Not Listed	Period 4	n	9	2	19	30
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC	NC, NC
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0	0.0, 0.0
	Overall	n	6	2	24	32
		Mean (SD)	0.00 (0.000)	NC	0.02 (0.094)	0.02 (0.082)
		95% CI	NC, NC	NC	-0.02, 0.07	-0.02, 0.05
		Median	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.5	0.0, 0.5

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
THSm2.2	Period 2	n	39	0	0	0	0	39
		Mean (SD)	14.73 (6.069)					14.73 (6.069)
		95% CI	12.76, 16.70					12.76, 16.70
		Median	14.42					14.42
		Min, Max	3.1, 35.5					3.1, 35.5
	Period 3	n	37	1	0	1	0	39
		Mean (SD)	15.99 (6.155)	NC		NC		15.18 (6.950)
		95% CI	13.93, 18.04	NC		NC		12.92, 17.44
		Median	15.97	NC		NC		15.59
		Min, Max	3.9, 33.5	NC		NC		0.0, 33.5
	Period 4	n	46	0	0	0	1	47
		Mean (SD)	14.52 (6.775)				NC	14.21 (7.028)
		95% CI	12.50, 16.53				NC	12.14, 16.27
		Median	14.81				NC	14.38
		Min, Max	0.7, 30.2				NC	0.0, 30.2

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
mCC/CC	Period 2	n	39	0	0	0	0	39
		Mean (SD)	0.01 (0.041)					0.01 (0.041)
		95% CI	-0.01, 0.03					-0.01, 0.03
		Median	0.00					0.00
		Min, Max	0.0, 0.2					0.0, 0.2
	Period 3	n	37	1	0	1	0	39
		Mean (SD)	0.00 (0.022)	NC		NC		0.01 (0.067)
		95% CI	-0.01, 0.02	NC		NC		-0.01, 0.04
		Median	0.00	NC		NC		0.00
		Min, Max	0.0, 0.1	NC		NC		0.0, 0.4
	Period 4	n	46	0	0	0	1	47
		Mean (SD)	0.01 (0.057)				NC	0.01 (0.057)
		95% CI	-0.01, 0.03				NC	-0.01, 0.03
		Median	0.00				NC	0.00
		Min, Max	0.0, 0.4				NC	0.0, 0.4

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Chew/Smokeless Tob.	Period 2	n	39	0	0	0	0	39
		Mean (SD)	0.00 (0.000)					0.00 (0.000)
		95% CI	NC, NC					NC, NC
		Median	0.00					0.00
		Min, Max	0.0, 0.0					0.0, 0.0
	Period 3	n	37	1	0	1	0	39
		Mean (SD)	0.00 (0.000)	NC		NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC		NC, NC
		Median	0.00	NC		NC		0.00
		Min, Max	0.0, 0.0	NC		NC		0.0, 0.0
	Period 4	n	46	0	0	0	1	47
		Mean (SD)	0.00 (0.000)				NC	0.00 (0.000)
		95% CI	NC, NC				NC	NC, NC
		Median	0.00				NC	0.00
		Min, Max	0.0, 0.0				NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Cigar/Cigarillo	Period 2	n	39	0	0	0	0	39
		Mean (SD)	0.00 (0.000)					0.00 (0.000)
		95% CI	NC, NC					NC, NC
		Median	0.00					0.00
		Min, Max	0.0, 0.0					0.0, 0.0
	Period 3	n	37	1	0	1	0	39
		Mean (SD)	0.00 (0.000)	NC		NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC		NC, NC
		Median	0.00	NC		NC		0.00
		Min, Max	0.0, 0.0	NC		NC		0.0, 0.0
	Period 4	n	46	0	0	0	1	47
		Mean (SD)	0.00 (0.000)				NC	0.00 (0.000)
		95% CI	NC, NC				NC	NC, NC
		Median	0.00				NC	0.00
		Min, Max	0.0, 0.0				NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
E-Cigarette	Period 2	n	39	0	0	0	0	39
		Mean (SD)	0.29 (1.694)					0.29 (1.694)
		95% CI	-0.27, 0.84					-0.27, 0.84
		Median	0.00					0.00
		Min, Max	0.0, 10.6					0.0, 10.6
	Period 3	n	37	1	0	1	0	39
		Mean (SD)	0.00 (0.000)	NC		NC		0.02 (0.108)
		95% CI	NC, NC	NC		NC		-0.02, 0.06
		Median	0.00	NC		NC		0.00
		Min, Max	0.0, 0.0	NC		NC		0.0, 0.7
	Period 4	n	46	0	0	0	1	47
		Mean (SD)	0.09 (0.420)				NC	0.09 (0.416)
		95% CI	-0.04, 0.22				NC	-0.04, 0.22
		Median	0.00				NC	0.00
		Min, Max	0.0, 2.4				NC	0.0, 2.4

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Gums	Period 2	n	39	0	0	0	0	39
		Mean (SD)	0.00 (0.000)					0.00 (0.000)
		95% CI	NC, NC					NC, NC
		Median	0.00					0.00
		Min, Max	0.0, 0.0					0.0, 0.0
	Period 3	n	37	1	0	1	0	39
		Mean (SD)	0.00 (0.000)	NC		NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC		NC, NC
		Median	0.00	NC		NC		0.00
		Min, Max	0.0, 0.0	NC		NC		0.0, 0.0
	Period 4	n	46	0	0	0	1	47
		Mean (SD)	0.00 (0.000)				NC	0.00 (0.000)
		95% CI	NC, NC				NC	NC, NC
		Median	0.00				NC	0.00
		Min, Max	0.0, 0.0				NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Inhaler	Period 2	n	39	0	0	0	0	39
		Mean (SD)	0.00 (0.000)					0.00 (0.000)
		95% CI	NC, NC					NC, NC
		Median	0.00					0.00
		Min, Max	0.0, 0.0					0.0, 0.0
	Period 3	n	37	1	0	1	0	39
		Mean (SD)	0.00 (0.000)	NC		NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC		NC, NC
		Median	0.00	NC		NC		0.00
		Min, Max	0.0, 0.0	NC		NC		0.0, 0.0
	Period 4	n	46	0	0	0	1	47
		Mean (SD)	0.00 (0.000)				NC	0.00 (0.000)
		95% CI	NC, NC				NC	NC, NC
		Median	0.00				NC	0.00
		Min, Max	0.0, 0.0				NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Lozenges	Period 2	n	39	0	0	0	0	39
		Mean (SD)	0.00 (0.000)					0.00 (0.000)
		95% CI	NC, NC					NC, NC
		Median	0.00					0.00
		Min, Max	0.0, 0.0					0.0, 0.0
	Period 3	n	37	1	0	1	0	39
		Mean (SD)	0.00 (0.000)	NC		NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC		NC, NC
		Median	0.00	NC		NC		0.00
		Min, Max	0.0, 0.0	NC		NC		0.0, 0.0
	Period 4	n	46	0	0	0	1	47
		Mean (SD)	0.00 (0.000)				NC	0.00 (0.000)
		95% CI	NC, NC				NC	NC, NC
		Median	0.00				NC	0.00
		Min, Max	0.0, 0.0				NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Nasal Spray	Period 2	n	39	0	0	0	0	39
		Mean (SD)	0.00 (0.000)					0.00 (0.000)
		95% CI	NC, NC					NC, NC
		Median	0.00					0.00
		Min, Max	0.0, 0.0					0.0, 0.0
	Period 3	n	37	1	0	1	0	39
		Mean (SD)	0.00 (0.000)	NC		NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC		NC, NC
		Median	0.00	NC		NC		0.00
		Min, Max	0.0, 0.0	NC		NC		0.0, 0.0
	Period 4	n	46	0	0	0	1	47
		Mean (SD)	0.00 (0.000)				NC	0.00 (0.000)
		95% CI	NC, NC				NC	NC, NC
		Median	0.00				NC	0.00
		Min, Max	0.0, 0.0				NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Other NRT	Period 2	n	39	0	0	0	0	39
		Mean (SD)	0.00 (0.000)					0.00 (0.000)
		95% CI	NC, NC					NC, NC
		Median	0.00					0.00
		Min, Max	0.0, 0.0					0.0, 0.0
	Period 3	n	37	1	0	1	0	39
		Mean (SD)	0.00 (0.000)	NC		NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC		NC, NC
		Median	0.00	NC		NC		0.00
		Min, Max	0.0, 0.0	NC		NC		0.0, 0.0
	Period 4	n	46	0	0	0	1	47
		Mean (SD)	0.00 (0.000)				NC	0.00 (0.000)
		95% CI	NC, NC				NC	NC, NC
		Median	0.00				NC	0.00
		Min, Max	0.0, 0.0				NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Patches	Period 2	n	39	0	0	0	0	39
		Mean (SD)	0.00 (0.000)					0.00 (0.000)
		95% CI	NC, NC					NC, NC
		Median	0.00					0.00
		Min, Max	0.0, 0.0					0.0, 0.0
	Period 3	n	37	1	0	1	0	39
		Mean (SD)	0.00 (0.000)	NC		NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC		NC, NC
		Median	0.00	NC		NC		0.00
		Min, Max	0.0, 0.0	NC		NC		0.0, 0.0
	Period 4	n	46	0	0	0	1	47
		Mean (SD)	0.00 (0.000)				NC	0.00 (0.000)
		95% CI	NC, NC				NC	NC, NC
		Median	0.00				NC	0.00
		Min, Max	0.0, 0.0				NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Pipes	Period 2	n	39	0	0	0	0	39
		Mean (SD)	0.00 (0.000)					0.00 (0.000)
		95% CI	NC, NC					NC, NC
		Median	0.00					0.00
		Min, Max	0.0, 0.0					0.0, 0.0
	Period 3	n	37	1	0	1	0	39
		Mean (SD)	0.00 (0.000)	NC		NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC		NC, NC
		Median	0.00	NC		NC		0.00
		Min, Max	0.0, 0.0	NC		NC		0.0, 0.0
	Period 4	n	46	0	0	0	1	47
		Mean (SD)	0.00 (0.000)				NC	0.00 (0.000)
		95% CI	NC, NC				NC	NC, NC
		Median	0.00				NC	0.00
		Min, Max	0.0, 0.0				NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	Period	Statistic	THSm2.2 Product Use Category					Overall THSm2.2
			THSm2.2 ([70-100]%)	Dual Use ([30-70]%)	CC ([0-30]%)	Not Abstinent	Abstinent	
Tob. Not Listed	Period 2	n	39	0	0	0	0	39
		Mean (SD)	0.02 (0.111)					0.02 (0.111)
		95% CI	-0.02, 0.06					-0.02, 0.06
		Median	0.00					0.00
		Min, Max	0.0, 0.7					0.0, 0.7
	Period 3	n	37	1	0	1	0	39
		Mean (SD)	0.00 (0.000)	NC		NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC		NC, NC
		Median	0.00	NC		NC		0.00
		Min, Max	0.0, 0.0	NC		NC		0.0, 0.0
	Period 4	n	46	0	0	0	1	47
		Mean (SD)	0.00 (0.000)				NC	0.00 (0.000)
		95% CI	NC, NC				NC	NC, NC
		Median	0.00				NC	0.00
		Min, Max	0.0, 0.0				NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	mCC Product Use Category		mCC
			Exclusively CC	Dual CC	
mCC/CC	Period 2	n	34	0	34
		Mean (SD)	14.91 (5.854)		14.91 (5.854)
		95% CI	12.86, 16.96		12.86, 16.96
		Median	14.94		14.94
		Min, Max	2.9, 31.0		2.9, 31.0
	Period 3	n	31	1	32
		Mean (SD)	15.52 (6.155)	NC	15.36 (6.125)
		95% CI	13.26, 17.78	NC	13.14, 17.57
		Median	14.43	NC	14.32
		Min, Max	2.7, 29.6	NC	2.7, 29.6
	Period 4	n	30	1	31
		Mean (SD)	15.70 (5.834)	NC	15.50 (5.840)
		95% CI	13.52, 17.89	NC	13.36, 17.65
		Median	14.52	NC	14.34
		Min, Max	8.6, 32.4	NC	8.6, 32.4

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	mCC Product Use Category		mCC
			Exclusively CC	Dual CC	
Chew/Smokeless Tob.	Period 2	n	34	0	34
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	31	1	32
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Period 4	n	30	1	31
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	mCC Product Use Category		mCC
			Exclusively CC	Dual CC	
Cigar/Cigarillo	Period 2	n	34	0	34
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	31	1	32
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Period 4	n	30	1	31
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	mCC Product Use Category		mCC
			Exclusively CC	Dual CC	
E-Cigarette	Period 2	n	34	0	34
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	31	1	32
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.006)
		95% CI	NC, NC	NC	-0.01, 0.01
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Period 4	n	30	1	31
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.019)
		95% CI	NC, NC	NC	-0.01, 0.02
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.1

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	mCC Product Use Category		mCC
			Exclusively CC	Dual CC	
Gums	Period 2	n	34	0	34
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	31	1	32
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Period 4	n	30	1	31
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	mCC Product Use Category		mCC
			Exclusively CC	Dual CC	
Inhaler	Period 2	n	34	0	34
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	31	1	32
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Period 4	n	30	1	31
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	mCC Product Use Category		mCC
			Exclusively CC	Dual CC	
Lozenges	Period 2	n	34	0	34
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	31	1	32
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Period 4	n	30	1	31
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	mCC Product Use Category		mCC
			Exclusively CC	Dual CC	
Nasal Spray	Period 2	n	34	0	34
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	31	1	32
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Period 4	n	30	1	31
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	mCC Product Use Category		mCC
			Exclusively CC	Dual CC	
Other NRT	Period 2	n	34	0	34
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	31	1	32
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Period 4	n	30	1	31
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	mCC Product Use Category		mCC
			Exclusively CC	Dual CC	
Patches	Period 2	n	34	0	34
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	31	1	32
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Period 4	n	30	1	31
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	mCC Product Use Category		mCC
			Exclusively CC	Dual CC	
Pipes	Period 2	n	34	0	34
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	31	1	32
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Period 4	n	30	1	31
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	mCC Product Use Category		mCC
			Exclusively CC	Dual CC	
Tob. Not Listed	Period 2	n	34	0	34
		Mean (SD)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC		NC, NC
		Median	0.00		0.00
		Min, Max	0.0, 0.0		0.0, 0.0
	Period 3	n	31	1	32
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0
	Period 4	n	30	1	31
		Mean (SD)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC	NC, NC
		Median	0.00	NC	0.00
		Min, Max	0.0, 0.0	NC	0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	SA Product Use Category			
			Abstinent	Predominantly Abstinent	Not Abstinent	SA
mCC/CC	Period 2	n	8	4	1	13
		Mean (SD)	0.00 (0.000)	0.05 (0.037)	NC	0.01 (0.030)
		95% CI	NC, NC	-0.02, 0.11	NC	-0.01, 0.04
		Median	0.00	0.06	NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.1	NC	0.0, 0.1
	Period 3	n	7	5	0	12
		Mean (SD)	0.00 (0.000)	0.05 (0.074)		0.02 (0.051)
		95% CI	NC, NC	-0.05, 0.14		-0.02, 0.06
		Median	0.00	0.00		0.00
		Min, Max	0.0, 0.0	0.0, 0.2		0.0, 0.2
	Period 4	n	7	2	0	9
		Mean (SD)	0.00 (0.000)	NC		0.02 (0.058)
		95% CI	NC, NC	NC		-0.03, 0.07
		Median	0.00	NC		0.00
		Min, Max	0.0, 0.0	NC		0.0, 0.2

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	SA Product Use Category			
			Abstinent	Predominantly Abstinent	Not Abstinent	SA
Chew/Smokeless Tob.	Period 2	n	8	4	1	13
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC	NC, NC
		Median	0.00	0.00	NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC	0.0, 0.0
	Period 3	n	7	5	0	12
		Mean (SD)	0.00 (0.000)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC	NC, NC		NC, NC
		Median	0.00	0.00		0.00
		Min, Max	0.0, 0.0	0.0, 0.0		0.0, 0.0
	Period 4	n	7	2	0	9
		Mean (SD)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC, NC
		Median	0.00	NC		0.00
		Min, Max	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	SA Product Use Category			
			Abstinent	Predominantly Abstinent	Not Abstinent	SA
Cigar/Cigarillo	Period 2	n	8	4	1	13
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC	NC, NC
		Median	0.00	0.00	NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC	0.0, 0.0
	Period 3	n	7	5	0	12
		Mean (SD)	0.00 (0.000)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC	NC, NC		NC, NC
		Median	0.00	0.00		0.00
		Min, Max	0.0, 0.0	0.0, 0.0		0.0, 0.0
	Period 4	n	7	2	0	9
		Mean (SD)	0.00 (0.000)	NC		0.01 (0.035)
		95% CI	NC, NC	NC		-0.02, 0.04
		Median	0.00	NC		0.00
		Min, Max	0.0, 0.0	NC		0.0, 0.1

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	SA Product Use Category			
			Abstinent	Predominantly Abstinent	Not Abstinent	SA
E-Cigarette	Period 2	n	8	4	1	13
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC	NC, NC
		Median	0.00	0.00	NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC	0.0, 0.0
	Period 3	n	7	5	0	12
		Mean (SD)	0.00 (0.000)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC	NC, NC		NC, NC
		Median	0.00	0.00		0.00
		Min, Max	0.0, 0.0	0.0, 0.0		0.0, 0.0
	Period 4	n	7	2	0	9
		Mean (SD)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC, NC
		Median	0.00	NC		0.00
		Min, Max	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	SA Product Use Category			
			Abstinent	Predominantly Abstinent	Not Abstinent	SA
Gums	Period 2	n	8	4	1	13
		Mean (SD)	0.00 (0.000)	0.02 (0.039)	NC	0.01 (0.022)
		95% CI	NC, NC	-0.05, 0.09	NC	-0.01, 0.02
		Median	0.00	0.00	NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.1	NC	0.0, 0.1
	Period 3	n	7	5	0	12
		Mean (SD)	0.00 (0.000)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC	NC, NC		NC, NC
		Median	0.00	0.00		0.00
		Min, Max	0.0, 0.0	0.0, 0.0		0.0, 0.0
	Period 4	n	7	2	0	9
		Mean (SD)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC, NC
		Median	0.00	NC		0.00
		Min, Max	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	SA Product Use Category			
			Abstinent	Predominantly Abstinent	Not Abstinent	SA
Inhaler	Period 2	n	8	4	1	13
		Mean (SD)	0.31 (0.871)	0.00 (0.000)	NC	0.19 (0.683)
		95% CI	-0.42, 1.04	NC, NC	NC	-0.23, 0.61
		Median	0.00	0.00	NC	0.00
		Min, Max	0.0, 2.5	0.0, 0.0	NC	0.0, 2.5
	Period 3	n	7	5	0	12
		Mean (SD)	1.13 (2.986)	0.00 (0.000)		0.66 (2.281)
		95% CI	-1.64, 3.90	NC, NC		-0.80, 2.11
		Median	0.00	0.00		0.00
		Min, Max	0.0, 7.9	0.0, 0.0		0.0, 7.9
	Period 4	n	7	2	0	9
		Mean (SD)	1.24 (3.272)	NC		0.96 (2.886)
		95% CI	-1.79, 4.27	NC		-1.26, 3.18
		Median	0.00	NC		0.00
		Min, Max	0.0, 8.7	NC		0.0, 8.7

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	SA Product Use Category			
			Abstinent	Predominantly Abstinent	Not Abstinent	SA
Lozenges	Period 2	n	8	4	1	13
		Mean (SD)	0.04 (0.109)	0.00 (0.000)	NC	0.02 (0.086)
		95% CI	-0.06, 0.13	NC, NC	NC	-0.03, 0.08
		Median	0.00	0.00	NC	0.00
		Min, Max	0.0, 0.3	0.0, 0.0	NC	0.0, 0.3
	Period 3	n	7	5	0	12
		Mean (SD)	0.06 (0.164)	0.00 (0.000)		0.04 (0.126)
		95% CI	-0.09, 0.22	NC, NC		-0.05, 0.12
		Median	0.00	0.00		0.00
		Min, Max	0.0, 0.4	0.0, 0.0		0.0, 0.4
	Period 4	n	7	2	0	9
		Mean (SD)	0.05 (0.144)	NC		0.04 (0.127)
		95% CI	-0.08, 0.19	NC		-0.06, 0.14
		Median	0.00	NC		0.00
		Min, Max	0.0, 0.4	NC		0.0, 0.4

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	SA Product Use Category			
			Abstinent	Predominantly Abstinent	Not Abstinent	SA
Nasal Spray	Period 2	n	8	4	1	13
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC	NC, NC
		Median	0.00	0.00	NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC	0.0, 0.0
	Period 3	n	7	5	0	12
		Mean (SD)	0.00 (0.000)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC	NC, NC		NC, NC
		Median	0.00	0.00		0.00
		Min, Max	0.0, 0.0	0.0, 0.0		0.0, 0.0
	Period 4	n	7	2	0	9
		Mean (SD)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC, NC
		Median	0.00	NC		0.00
		Min, Max	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	SA Product Use Category			
			Abstinent	Predominantly Abstinent	Not Abstinent	SA
Other NRT	Period 2	n	8	4	1	13
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC	NC, NC
		Median	0.00	0.00	NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC	0.0, 0.0
	Period 3	n	7	5	0	12
		Mean (SD)	0.00 (0.000)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC	NC, NC		NC, NC
		Median	0.00	0.00		0.00
		Min, Max	0.0, 0.0	0.0, 0.0		0.0, 0.0
	Period 4	n	7	2	0	9
		Mean (SD)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC, NC
		Median	0.00	NC		0.00
		Min, Max	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	SA Product Use Category			
			Abstinent	Predominantly Abstinent	Not Abstinent	SA
Patches	Period 2	n	8	4	1	13
		Mean (SD)	0.06 (0.164)	0.21 (0.424)	NC	0.10 (0.258)
		95% CI	-0.08, 0.20	-0.47, 0.89	NC	-0.06, 0.26
		Median	0.00	0.00	NC	0.00
		Min, Max	0.0, 0.5	0.0, 0.8	NC	0.0, 0.8
	Period 3	n	7	5	0	12
		Mean (SD)	0.00 (0.000)	0.07 (0.164)		0.03 (0.106)
		95% CI	NC, NC	-0.14, 0.28		-0.04, 0.10
		Median	0.00	0.00		0.00
		Min, Max	0.0, 0.0	0.0, 0.4		0.0, 0.4
	Period 4	n	7	2	0	9
		Mean (SD)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC, NC
		Median	0.00	NC		0.00
		Min, Max	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	SA Product Use Category			
			Abstinent	Predominantly Abstinent	Not Abstinent	SA
Pipes	Period 2	n	8	4	1	13
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC	NC, NC
		Median	0.00	0.00	NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC	0.0, 0.0
	Period 3	n	7	5	0	12
		Mean (SD)	0.00 (0.000)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC	NC, NC		NC, NC
		Median	0.00	0.00		0.00
		Min, Max	0.0, 0.0	0.0, 0.0		0.0, 0.0
	Period 4	n	7	2	0	9
		Mean (SD)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC, NC
		Median	0.00	NC		0.00
		Min, Max	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.

**Table 15.2.2.5.2 Summary of Average Reported Daily Product Use by Product Use Category During the Ambulatory Period - PP Set**

Product	period	Statistic	SA Product Use Category			
			Abstinent	Predominantly Abstinent	Not Abstinent	SA
Tob. Not Listed	Period 2	n	8	4	1	13
		Mean (SD)	0.00 (0.000)	0.04 (0.077)	NC	0.02 (0.055)
		95% CI	NC, NC	-0.09, 0.17	NC	-0.02, 0.06
		Median	0.00	0.00	NC	0.00
		Min, Max	0.0, 0.0	0.0, 0.2	NC	0.0, 0.2
	Period 3	n	7	5	0	12
		Mean (SD)	0.00 (0.000)	0.00 (0.000)		0.00 (0.000)
		95% CI	NC, NC	NC, NC		NC, NC
		Median	0.00	0.00		0.00
		Min, Max	0.0, 0.0	0.0, 0.0		0.0, 0.0
	Period 4	n	7	2	0	9
		Mean (SD)	0.00 (0.000)	NC		0.00 (0.000)
		95% CI	NC, NC	NC		NC, NC
		Median	0.00	NC		0.00
		Min, Max	0.0, 0.0	NC		0.0, 0.0

Note: CC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: NC = Not calculated.

Note: Tob. Not Listed refers to other tobacco products not previously listed.



15.2.3 Primary Endpoints Summary Tables



Table 15.2.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - PP Set

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
MHBMA (pg/mg creat)				
Day 5	n	65	30	
	Geometric LS Mean (CV%)	110.96	882.25	12.58 (76.92)
	95% CI	93.49, 131.68	687.25, 1132.57	9.27, 17.05
	p-value (one-sided)			<0.001
Day 90	n	43	29	
	Geometric LS Mean (CV%)	213.78	1154.52	18.52 (85.36)
	95% CI	169.12, 270.22	875.26, 1522.88	12.85, 26.67
	p-value (one-sided)			<0.001

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.



Table 15.2.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - PP Set

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
3-HPMA (ng/mg creat)				
Day 5	n	67	30	
	Geometric LS Mean (CV%)	278.13	607.68	45.77 (36.45)
	95% CI	254.95, 303.43	534.34, 691.09	39.22, 53.41
	p-value (one-sided)			<0.001
Day 90	n	43	29	
	Geometric LS Mean (CV%)	310.81	597.49	52.02 (53.49)
	95% CI	265.74, 363.52	495.28, 720.79	40.80, 66.33
	p-value (one-sided)			<0.001

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
S-PMA (pg/mg creat)				
Day 5	n	65	30	
	Geometric LS Mean (CV%)	134.11	1065.91	12.58 (69.68)
	95% CI	114.63, 156.90	848.45, 1339.09	9.54, 16.58
	p-value (one-sided)			<0.001
Day 90	n	43	29	
	Geometric LS Mean (CV%)	267.16	1209.91	22.08 (133.71)
	95% CI	194.79, 366.41	829.06, 1765.73	13.52, 36.06
	p-value (one-sided)			<0.001

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
COHb (%)				
Day 5	n	74	34	
	Geometric LS Mean (CV%)	2.33	6.11	38.14 (26.50)
	95% CI	2.19, 2.48	5.58, 6.68	34.24, 42.47
	p-value (one-sided)			<0.001
Day 90	n	47	32	
	Geometric LS Mean (CV%)	2.65	5.66	46.76 (36.30)
	95% CI	2.38, 2.94	4.99, 6.42	39.75, 55.00
	p-value (one-sided)			<0.001

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.1.1 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Total NNAL (pg/mg creat)				
Day 5	n	67	30	
	Geometric LS Mean (CV%)	55.44	126.55	43.81 (40.70)
	95% CI	50.33, 61.07	109.79, 145.86	36.92, 51.97
	p-value (one-sided)			<0.001
Day 90	n	43	29	
	Geometric LS Mean (CV%)	41.05	155.45	26.41 (106.00)
	95% CI	31.28, 53.86	112.46, 214.88	17.31, 40.26
	p-value (one-sided)			<0.001

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
MHBMA (pg/mg creat)				
Day 5	n	64	29	
	Geometric LS Mean (CV%)	112.13	907.64	12.35 (77.34)
	95% CI	94.27, 133.38	703.51, 1170.99	9.07, 16.83
	p-value (one-sided)			<0.001
Day 90	n	43	28	
	Geometric LS Mean (CV%)	212.93	1145.94	18.58 (86.10)
	95% CI	168.13, 269.67	863.22, 1521.26	12.81, 26.94
	p-value (one-sided)			<0.001

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary analysis, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary analysis, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
3-HPMA (ng/mg creat) Day 5	n	66	29	
	Geometric LS Mean (CV%)	276.44	593.00	46.62 (36.26)
	95% CI	253.28, 301.72	520.61, 675.46	39.90, 54.47
	p-value (one-sided)			<0.001
Day 90	n	43	28	
	Geometric LS Mean (CV%)	310.61	593.45	52.34 (53.84)
	95% CI	265.30, 363.65	490.06, 718.66	40.89, 66.99
	p-value (one-sided)			<0.001

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary analysis, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary analysis, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
S-PMA (pg/mg creat)				
Day 5	n	64	29	
	Geometric LS Mean (CV%)	133.23	1057.79	12.60 (70.33)
	95% CI	113.57, 156.29	836.85, 1337.06	9.50, 16.70
	p-value (one-sided)			<0.001
Day 90	n	43	28	
	Geometric LS Mean (CV%)	265.27	1184.57	22.39 (134.93)
	95% CI	192.98, 364.62	805.51, 1742.03	13.60, 36.86
	p-value (one-sided)			<0.001

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary analysis, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary analysis, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
COHb (%)				
Day 5	n	63	29	
	Geometric LS Mean (CV%)	2.35	6.33	37.06 (21.89)
	95% CI	2.21, 2.48	5.83, 6.86	33.64, 40.82
	p-value (one-sided)			<0.001
Day 90	n	39	24	
	Geometric LS Mean (CV%)	2.59	5.98	43.28 (31.70)
	95% CI	2.33, 2.87	5.26, 6.79	36.79, 50.92
	p-value (one-sided)			<0.001

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary analysis, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary analysis, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.1.2 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective using Mixed Model - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Total NNAL (pg/mg creat)				
Day 5	n	66	29	
	Geometric LS Mean (CV%)	55.14	123.76	44.55 (40.78)
	95% CI	49.99, 60.81	107.06, 143.06	37.44, 53.01
	p-value (one-sided)			<0.001
Day 90	n	43	28	
	Geometric LS Mean (CV%)	41.03	150.26	27.30 (105.81)
	95% CI	31.27, 53.82	108.20, 208.67	17.83, 41.80
	p-value (one-sided)			<0.001

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary analysis, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary analysis, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
MHBMA (pg/mg creat)				
Day 5	n	65	30	
	Geometric LS Mean (CV%)	110.96	882.25	12.58 (76.92)
	95% CI	93.49, 131.68	687.25, 1132.57	9.27, 17.05
	p-value (one-sided)			<0.001
Day 90	n	37	29	
	Geometric LS Mean (CV%)	218.64	1142.42	19.14 (80.19)
	95% CI	172.16, 277.67	877.11, 1487.99	13.35, 27.43
	p-value (one-sided)			<0.001

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
3-HPMA (ng/mg creat)				
Day 5	n	67	30	
	Geometric LS Mean (CV%)	278.13	607.68	45.77 (36.45)
	95% CI	254.95, 303.43	534.34, 691.09	39.22, 53.41
	p-value (one-sided)			<0.001
Day 90	n	37	29	
	Geometric LS Mean (CV%)	309.35	600.58	51.51 (54.85)
	95% CI	260.33, 367.58	495.48, 727.98	39.74, 66.75
	p-value (one-sided)			<0.001

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
S-PMA (pg/mg creat)				
Day 5	n	65	30	
	Geometric LS Mean (CV%)	134.11	1065.91	12.58 (69.68)
	95% CI	114.63, 156.90	848.45, 1339.09	9.54, 16.58
	p-value (one-sided)			<0.001
Day 90	n	37	29	
	Geometric LS Mean (CV%)	268.15	1200.75	22.33 (128.49)
	95% CI	192.43, 373.66	829.48, 1738.19	13.55, 36.79
	p-value (one-sided)			<0.001

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
COHb (%)				
Day 5	n	74	34	
	Geometric LS Mean (CV%)	2.33	6.11	38.14 (26.50)
	95% CI	2.19, 2.48	5.58, 6.68	34.24, 42.47
	p-value (one-sided)			<0.001
Day 90	n	41	31	
	Geometric LS Mean (CV%)	2.63	5.77	45.55 (31.62)
	95% CI	2.38, 2.90	5.16, 6.46	39.24, 52.86
	p-value (one-sided)			<0.001

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.1.3 Sensitivity Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC for the Primary Objective - Compliant Population**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Total NNAL (pg/mg creat)				
Day 5	n	67	30	
	Geometric LS Mean (CV%)	55.44	126.55	43.81 (40.70)
	95% CI	50.33, 61.07	109.79, 145.86	36.92, 51.97
	p-value (one-sided)			<0.001
Day 90	n	37	29	
	Geometric LS Mean (CV%)	42.84	152.46	28.10 (110.39)
	95% CI	31.72, 57.85	109.17, 212.89	17.89, 44.13
	p-value (one-sided)			<0.001

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
MHBMA (pg/mg creat)						
Day 5	n	65	30	21		
	Geometric LS Mean (CV%)	110.96	882.25	94.97	12.58 (76.92)	116.84 (76.92)
	95% CI	93.49, 131.68	687.25, 1132.57	70.67, 127.61	9.27, 17.05	83.12, 164.24
	p-value (one-sided)				<0.001	
Day 90	n	43	29	9		
	Geometric LS Mean (CV%)	213.78	1154.52	330.06	18.52 (85.36)	64.77 (85.36)
	95% CI	169.12, 270.22	875.26, 1522.88	198.39, 549.13	12.85, 26.67	36.88, 113.74
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
3-HPMA (ng/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	278.13	607.68	152.05	45.77 (36.45)	182.92 (36.45)
	95% CI	254.95, 303.43	534.34, 691.09	130.47, 177.19	39.22, 53.41	153.51, 217.97
	p-value (one-sided)				<0.001	
Day 90	n	43	29	9		
	Geometric LS Mean (CV%)	310.81	597.49	210.94	52.02 (53.49)	147.34 (53.49)
	95% CI	265.74, 363.52	495.28, 720.79	149.75, 297.13	40.80, 66.33	101.23, 214.45
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-PMA (pg/mg creat)						
Day 5	n	65	30	21		
	Geometric LS Mean (CV%)	134.11	1065.91	131.05	12.58 (69.68)	102.34 (69.68)
	95% CI	114.63, 156.90	848.45, 1339.09	99.78, 172.13	9.54, 16.58	74.82, 139.97
	p-value (one-sided)				<0.001	
Day 90	n	43	29	9		
	Geometric LS Mean (CV%)	267.16	1209.91	227.36	22.08 (133.71)	117.51 (133.71)
	95% CI	194.79, 366.41	829.06, 1765.73	114.21, 452.57	13.52, 36.06	55.32, 249.57
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
COHb (%)						
Day 5	n	74	34	23		
	Geometric LS Mean (CV%)	2.33	6.11	2.39	38.14 (26.50)	97.30 (26.50)
	95% CI	2.19, 2.48	5.58, 6.68	2.14, 2.67	34.24, 42.47	86.02, 110.05
	p-value (one-sided)				<0.001	
Day 90	n	47	32	9		
	Geometric LS Mean (CV%)	2.65	5.66	2.92	46.76 (36.30)	90.50 (36.30)
	95% CI	2.38, 2.94	4.99, 6.42	2.30, 3.72	39.75, 55.00	69.88, 117.19
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.2 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total NNAL (pg/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	55.44	126.55	55.44	43.81 (40.70)	99.99 (40.70)
	95% CI	50.33, 61.07	109.79, 145.86	46.79, 65.70	36.92, 51.97	82.32, 121.44
	p-value (one-sided)				<0.001	
Day 90	n	43	29	9		
	Geometric LS Mean (CV%)	41.05	155.45	54.03	26.41 (106.00)	75.98 (106.00)
	95% CI	31.28, 53.86	112.46, 214.88	30.00, 97.28	17.31, 40.26	39.92, 144.61
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
MHBMA (pg/mg creat)						
Day 5	n	69	36	36		
	Geometric LS Mean (CV%)	112.37	991.16	146.94	11.34 (98.10)	76.48 (98.10)
	95% CI	92.15, 137.04	754.96, 1301.24	111.86, 193.00	8.09, 15.89	54.64, 107.04
	p-value (one-sided)				<0.001	
Day 90	n	69	36	36		
	Geometric LS Mean (CV%)	265.12	1321.70	534.42	20.06 (92.19)	49.61 (92.19)
	95% CI	219.35, 320.44	1019.07, 1714.20	411.86, 693.45	14.53, 27.69	35.98, 68.40
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
3-HPMA (ng/mg creat)						
Day 5	n	71	36	36		
	Geometric LS Mean (CV%)	283.73	653.64	195.41	43.41 (47.20)	145.20 (47.20)
	95% CI	255.07, 315.61	563.44, 758.27	168.37, 226.79	36.18, 52.08	121.01, 174.21
	p-value (one-sided)				<0.001	
Day 90	n	71	36	36		
	Geometric LS Mean (CV%)	324.87	658.35	301.54	49.35 (57.40)	107.74 (57.40)
	95% CI	286.21, 368.76	551.73, 785.58	252.57, 359.99	39.73, 61.29	86.74, 133.82
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-PMA (pg/mg creat)						
Day 5	n	69	36	36		
	Geometric LS Mean (CV%)	137.39	1267.99	179.58	10.84 (91.65)	76.50 (91.65)
	95% CI	113.88, 165.74	979.70, 1641.12	138.57, 232.73	7.88, 14.89	55.64, 105.20
	p-value (one-sided)				<0.001	
Day 90	n	69	36	36		
	Geometric LS Mean (CV%)	393.88	1447.74	555.01	27.21 (145.91)	70.97 (145.91)
	95% CI	304.74, 509.11	1017.35, 2060.20	389.32, 791.20	17.61, 42.02	45.91, 109.71
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

Appendix 15.3.3.1 and 15.3.3.2

Study ID: ZRHM-REXA-08-US

Program: t_anlcohb.sas

Status: Final

28APR16

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**Table 15.2.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
COHb (%)						
Day 5	n	78	40	35		
	Geometric LS Mean (CV%)	2.35	6.28	2.48	37.44 (29.46)	94.71 (29.46)
	95% CI	2.20, 2.51	5.73, 6.88	2.25, 2.74	33.50, 41.84	84.32, 106.37
	p-value (one-sided)				<0.001	
Day 90	n	78	40	35		
	Geometric LS Mean (CV%)	3.00	5.86	3.68	51.17 (39.16)	81.52 (39.16)
	95% CI	2.75, 3.27	5.20, 6.60	3.23, 4.18	44.24, 59.19	70.02, 94.92
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

Appendix 15.3.3.1 and 15.3.3.2

Study ID: ZRHM-REXA-08-US

Program: t_anlcohb.sas

Status: Final

28APR16

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**Table 15.2.3.3 Analysis of COHb, MHBMA, 3-HPMA, S-PMA, and Total NNAL on Day 5/90 Visit for THS 2.2 Menthol versus mCC and SA - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total NNAL (pg/mg creat)						
Day 5	n	71	36	36		
	Geometric LS Mean (CV%)	57.32	136.18	60.37	42.09 (44.70)	94.95 (44.70)
	95% CI	51.79, 63.45	118.26, 156.80	52.39, 69.57	35.41, 50.04	79.82, 112.95
	p-value (one-sided)				<0.001	
Day 90	n	71	36	36		
	Geometric LS Mean (CV%)	57.06	181.85	86.15	31.38 (109.38)	66.24 (109.38)
	95% CI	46.21, 70.46	135.65, 243.79	64.16, 115.66	21.90, 44.95	46.18, 95.02
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

Note: For the primary objective, Total NNAL is evaluated at Day 90 while the other biomarkers are evaluated at Day 5. For the secondary objective, Total NNAL is evaluated at Day 5 while the other biomarkers are evaluated at Day 90.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Exhaled CO (ppm)						
Day 5	n	75	35	24		
	LS Mean	2.20	22.16	2.03	-19.96	0.17
	95% CI	1.25, 3.15	20.79, 23.54	0.37, 3.69	-21.62, -18.31	-1.72, 2.07
	p-value (one-sided)				<0.001	
Day 90	n	47	32	9		
	LS Mean	4.99	19.61	5.09	-14.62	-0.10
	95% CI	3.03, 6.94	17.26, 21.96	0.59, 9.59	-17.67, -11.57	-4.99, 4.78
	p-value (one-sided)				<0.001	

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total 1-OHP (pg/mg creat)						
Day 5	n	65	30	22		
	Geometric LS Mean (CV%)	60.41	125.57	57.56	48.11 (31.01)	104.96 (31.01)
	95% CI	55.96, 65.21	112.49, 140.18	50.53, 65.56	42.11, 54.96	90.17, 122.16
	p-value (one-sided)				<0.001	
Day 90	n	43	29	9		
	Geometric LS Mean (CV%)	108.70	163.56	94.74	66.46 (49.92)	114.73 (49.92)
	95% CI	93.47, 126.40	137.15, 195.06	68.39, 131.25	52.67, 83.84	79.83, 164.88
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NNN (pg/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	0.91	6.44	0.13	14.06 (78.93)	678.32 (78.93)
	95% CI	0.76, 1.08	4.99, 8.29	0.09, 0.19	10.38, 19.06	479.07, 960.44
	p-value (one-sided)				<0.001	
Day 90	n	43	29	9		
	Geometric LS Mean (CV%)	0.90	5.04	0.33	17.80 (87.18)	268.55 (87.18)
	95% CI	0.70, 1.14	3.80, 6.68	0.20, 0.56	12.31, 25.75	153.11, 471.04
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
4-ABP (pg/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	1.86	9.63	1.54	19.31 (64.86)	120.62 (64.86)
	95% CI	1.60, 2.16	7.76, 11.95	1.19, 2.00	14.90, 25.01	89.83, 161.97
	p-value (one-sided)				<0.001	
Day 90	n	43	29	9		
	Geometric LS Mean (CV%)	3.30	11.57	3.24	28.48 (91.54)	101.66 (91.54)
	95% CI	2.58, 4.21	8.64, 15.48	1.90, 5.52	19.51, 41.58	56.81, 181.90
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
1-NA (pg/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	2.67	64.48	2.29	4.15 (57.67)	116.96 (57.67)
	95% CI	2.34, 3.06	53.07, 78.34	1.81, 2.89	3.28, 5.25	89.59, 152.70
	p-value (one-sided)				<0.001	
Day 90	n	43	29	9		
	Geometric LS Mean (CV%)	8.67	60.70	6.48	14.29 (102.76)	133.95 (102.76)
	95% CI	6.64, 11.32	44.20, 83.37	3.63, 11.54	9.47, 21.56	71.10, 252.34
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
2-NA (pg/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	2.24	17.11	2.06	13.12 (54.65)	109.03 (54.65)
	95% CI	1.97, 2.55	14.20, 20.61	1.64, 2.57	10.49, 16.40	84.55, 140.59
	p-value (one-sided)				<0.001	
Day 90	n	43	29	9		
	Geometric LS Mean (CV%)	2.82	17.57	3.37	16.04 (68.65)	83.61 (68.65)
	95% CI	2.32, 3.43	13.93, 22.17	2.20, 5.15	11.87, 21.67	52.57, 132.97
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
o-tol (pg/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	44.82	91.98	34.82	48.72 (49.32)	128.72 (49.32)
	95% CI	39.95, 50.28	77.53, 109.12	28.44, 42.62	39.70, 59.79	102.10, 162.28
	p-value (one-sided)				<0.001	
Day 90	n	43	29	9		
	Geometric LS Mean (CV%)	47.06	108.71	42.00	43.29 (68.48)	112.05 (68.48)
	95% CI	38.80, 57.08	86.03, 137.37	27.57, 63.97	32.00, 58.55	70.79, 177.37
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CEMA (ng/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	13.98	81.15	13.21	17.23 (42.01)	105.84 (42.01)
	95% CI	12.65, 15.45	70.07, 93.98	11.09, 15.74	14.44, 20.55	86.65, 129.27
	p-value (one-sided)				<0.001	
Day 90	n	43	29	9		
	Geometric LS Mean (CV%)	11.88	83.10	14.45	14.29 (121.48)	82.18 (121.48)
	95% CI	8.82, 15.98	58.23, 118.60	7.58, 27.55	9.01, 22.67	40.63, 166.22
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HEMA (pg/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	1160.03	2959.77	1108.66	39.19 (55.70)	104.63 (55.70)
	95% CI	1019.67, 1319.71	2451.31, 3573.68	885.11, 1388.68	31.22, 49.20	80.79, 135.51
	p-value (one-sided)				<0.001	
Day 90	n	43	29	9		
	Geometric LS Mean (CV%)	1394.63	3623.38	1793.97	38.49 (70.07)	77.74 (70.07)
	95% CI	1142.35, 1702.63	2862.50, 4586.52	1169.58, 2751.67	28.28, 52.38	48.68, 124.14
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
B[a]P (fg/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	32.09	110.89	21.07	28.94 (54.77)	152.32 (54.77)
	95% CI	28.22, 36.49	92.04, 133.59	16.78, 26.45	23.14, 36.20	116.94, 198.39
	p-value (one-sided)				<0.001	
Day 90	n	43	29	9		
	Geometric LS Mean (CV%)	54.65	126.12	58.81	43.33 (71.37)	92.93 (71.37)
	95% CI	44.49, 67.12	99.20, 160.34	37.92, 91.20	31.52, 59.57	57.11, 151.22
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HMPMA (ng/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	95.32	249.13	78.81	38.26 (53.56)	120.95 (53.56)
	95% CI	84.22, 107.89	207.58, 298.99	63.39, 97.97	30.73, 47.64	94.28, 155.18
	p-value (one-sided)				<0.001	
Day 90	n	43	29	9		
	Geometric LS Mean (CV%)	107.87	217.35	105.34	49.63 (64.74)	102.41 (64.74)
	95% CI	89.65, 129.80	174.31, 271.03	70.57, 157.24	37.25, 66.13	66.08, 158.69
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-BMA (pg/mg creat)						
Day 5	n	65	30	21		
	Geometric LS Mean (CV%)	3745.43	3227.50	4623.62	116.05 (62.06)	81.01 (62.06)
	95% CI	3248.55, 4318.30	2623.07, 3971.21	3609.72, 5922.31	90.29, 149.14	60.97, 107.63
	p-value (one-sided)				0.121	
Day 90	n	43	29	9		
	Geometric LS Mean (CV%)	3793.16	3452.68	4304.05	109.86 (91.35)	88.13 (91.35)
	95% CI	2971.61, 4841.84	2582.22, 4616.56	2537.57, 7300.23	75.25, 160.39	49.39, 157.24
	p-value (one-sided)					

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NEQ (mg/g creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	7.06	8.08	0.22	87.33 (52.06)	3137.39 (52.06)
	95% CI	6.25, 7.97	6.76, 9.67	0.18, 0.28	70.49, 108.18	2460.75, 4000.09
	p-value (one-sided)				0.106	
Day 90	n	43	29	9		
	Geometric LS Mean (CV%)	6.59	6.84	0.98	96.30 (89.23)	672.18 (89.23)
	95% CI	5.19, 8.37	5.13, 9.12	0.58, 1.65	66.43, 139.59	381.00, 1185.86
	p-value (one-sided)					

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
MHBMA (ng)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	181.31	1442.98	155.91	12.56 (76.87)	116.29 (76.87)
	95% CI	153.25, 214.51	1123.53, 1853.26	116.03, 209.49	9.28, 17.01	82.84, 163.26
	p-value (one-sided)				<0.001	
Day 90	n	45	29	9		
	Geometric LS Mean (CV%)	364.12	1873.19	540.23	19.44 (87.08)	67.40 (87.08)
	95% CI	289.10, 458.61	1413.54, 2482.31	321.27, 908.42	13.48, 28.03	38.05, 119.37
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
3-HPMA (ug)						
Day 5	n	70	31	22		
	Geometric LS Mean (CV%)	461.90	1023.21	257.50	45.14 (39.63)	179.38 (39.63)
	95% CI	421.33, 506.38	892.87, 1172.57	218.98, 302.81	38.33, 53.17	149.05, 215.86
	p-value (one-sided)				<0.001	
Day 90	n	45	29	9		
	Geometric LS Mean (CV%)	503.29	969.81	340.26	51.90 (51.59)	147.91 (51.59)
	95% CI	434.36, 583.15	809.04, 1162.52	243.54, 475.40	41.11, 65.50	102.85, 212.72
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-PMA (ng)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	223.78	1773.28	217.73	12.62 (71.62)	102.78 (71.62)
	95% CI	191.09, 262.05	1404.10, 2239.53	164.76, 287.72	9.52, 16.72	74.69, 141.42
	p-value (one-sided)				<0.001	
Day 90	n	45	29	9		
	Geometric LS Mean (CV%)	465.32	1977.22	378.40	23.53 (137.61)	122.97 (137.61)
	95% CI	340.31, 636.24	1346.26, 2903.89	187.25, 764.68	14.36, 38.57	57.16, 264.55
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total NNAL (ng)						
Day 5	n	69	30	21		
	Geometric LS Mean (CV%)	90.31	209.49	91.63	43.11 (43.12)	98.56 (43.12)
	95% CI	81.70, 99.83	180.36, 243.32	76.62, 109.58	36.03, 51.58	80.35, 120.88
	p-value (one-sided)				<0.001	
Day 90	n	45	29	9		
	Geometric LS Mean (CV%)	67.01	248.32	87.42	26.99 (112.58)	76.66 (112.58)
	95% CI	50.91, 88.20	177.21, 347.97	47.32, 161.49	17.48, 41.66	39.29, 149.56
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total 1-OHP (ng)						
Day 5	n	66	30	22		
	Geometric LS Mean (CV%)	101.23	209.34	94.13	48.36 (37.61)	107.54 (37.61)
	95% CI	92.44, 110.85	183.47, 238.85	80.42, 110.17	41.22, 56.72	89.58, 129.11
	p-value (one-sided)				<0.001	
Day 90	n	44	29	9		
	Geometric LS Mean (CV%)	179.24	264.76	152.42	67.70 (50.27)	117.60 (50.27)
	95% CI	154.34, 208.15	221.70, 316.18	109.18, 212.77	53.62, 85.48	81.25, 170.21
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NNN (ng)						
Day 5	n	69	30	21		
	Geometric LS Mean (CV%)	1.46	10.50	0.22	13.92 (82.33)	674.45 (82.33)
	95% CI	1.22, 1.75	8.08, 13.63	0.15, 0.30	10.18, 19.03	471.67, 964.39
	p-value (one-sided)				<0.001	
Day 90	n	45	29	9		
	Geometric LS Mean (CV%)	1.47	7.95	0.53	18.45 (90.58)	279.26 (90.58)
	95% CI	1.15, 1.86	5.95, 10.62	0.31, 0.89	12.70, 26.79	157.17, 496.18
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
4-ABP (ng)						
Day 5	n	70	31	22		
	Geometric LS Mean (CV%)	3.13	16.05	2.48	19.48 (63.42)	125.86 (63.42)
	95% CI	2.71, 3.60	13.03, 19.75	1.94, 3.18	15.18, 24.99	94.90, 166.92
	p-value (one-sided)				<0.001	
Day 90	n	45	29	9		
	Geometric LS Mean (CV%)	5.60	18.67	5.01	30.01 (93.89)	111.97 (93.89)
	95% CI	4.40, 7.14	13.88, 25.12	2.90, 8.62	20.50, 43.94	62.01, 202.16
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
1-NA (ng)						
Day 5	n	70	31	22		
	Geometric LS Mean (CV%)	4.35	106.92	3.69	4.07 (55.99)	117.94 (55.99)
	95% CI	3.83, 4.94	88.75, 128.80	2.95, 4.61	3.25, 5.10	91.53, 151.98
	p-value (one-sided)				<0.001	
Day 90	n	45	29	9		
	Geometric LS Mean (CV%)	14.67	97.96	10.11	14.98 (105.15)	145.18 (105.15)
	95% CI	11.29, 19.07	70.99, 135.18	5.60, 18.23	9.90, 22.65	76.43, 275.78
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
2-NA (ng)						
Day 5	n	70	31	22		
	Geometric LS Mean (CV%)	3.62	28.33	3.33	12.78 (51.14)	108.89 (51.14)
	95% CI	3.22, 4.07	23.85, 33.66	2.71, 4.09	10.40, 15.72	86.17, 137.59
	p-value (one-sided)				<0.001	
Day 90	n	45	29	9		
	Geometric LS Mean (CV%)	4.83	28.30	5.32	17.06 (74.20)	90.70 (74.20)
	95% CI	3.94, 5.91	22.10, 36.24	3.38, 8.38	12.41, 23.43	55.41, 148.45
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
o-tol (ng)						
Day 5	n	70	31	22		
	Geometric LS Mean (CV%)	72.02	152.19	56.60	47.32 (48.14)	127.23 (48.14)
	95% CI	64.52, 80.39	129.22, 179.23	46.62, 68.72	38.89, 57.58	101.96, 158.76
	p-value (one-sided)				<0.001	
Day 90	n	45	29	9		
	Geometric LS Mean (CV%)	75.39	174.61	66.50	43.18 (66.17)	113.36 (66.17)
	95% CI	62.79, 90.51	139.24, 218.96	44.11, 100.26	32.28, 57.75	72.62, 176.96
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CEMA (ug)						
Day 5	n	70	31	22		
	Geometric LS Mean (CV%)	23.56	136.87	22.29	17.21 (45.68)	105.70 (45.68)
	95% CI	21.21, 26.16	117.17, 159.88	18.53, 26.81	14.28, 20.74	85.60, 130.53
	p-value (one-sided)				<0.001	
Day 90	n	45	29	9		
	Geometric LS Mean (CV%)	20.54	134.84	23.64	15.23 (126.86)	86.88 (126.86)
	95% CI	15.26, 27.64	93.57, 194.32	12.16, 45.96	9.52, 24.36	42.19, 178.88
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HEMA (ng)						
Day 5	n	70	31	22		
	Geometric LS Mean (CV%)	1908.19	4934.43	1833.48	38.67 (55.19)	104.07 (55.19)
	95% CI	1684.39, 2161.72	4106.13, 5929.82	1473.51, 2281.40	30.99, 48.25	81.01, 133.71
	p-value (one-sided)				<0.001	
Day 90	n	45	29	9		
	Geometric LS Mean (CV%)	2319.88	5877.88	2943.13	39.47 (70.42)	78.82 (70.42)
	95% CI	1910.70, 2816.68	4639.23, 7447.24	1915.35, 4522.43	29.07, 53.59	49.32, 125.96
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
B[a]P (pg) Day 5	n	69	30	21		
	Geometric LS Mean (CV%)	54.24	183.37	33.80	29.58 (53.63)	160.48 (53.63)
	95% CI	47.93, 61.37	152.79, 220.07	26.99, 42.32	23.77, 36.81	123.78, 208.04
	p-value (one-sided)				<0.001	
Day 90	n	45	29	9		
	Geometric LS Mean (CV%)	91.91	203.76	95.69	45.11 (71.91)	96.05 (71.91)
	95% CI	75.29, 112.20	159.97, 259.52	61.35, 149.23	32.89, 61.85	58.84, 156.78
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HMPMA (ug)						
Day 5	n	70	31	22		
	Geometric LS Mean (CV%)	158.79	427.05	136.16	37.18 (55.13)	116.62 (55.13)
	95% CI	140.26, 179.76	355.41, 513.12	109.46, 169.38	29.82, 46.36	90.86, 149.67
	p-value (one-sided)				<0.001	
Day 90	n	45	29	9		
	Geometric LS Mean (CV%)	173.20	352.77	173.68	49.10 (61.54)	99.72 (61.54)
	95% CI	145.84, 205.68	285.58, 435.76	118.21, 255.17	37.41, 64.42	65.61, 151.57
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-BMA (ng)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	6326.41	5397.72	7735.76	117.21 (63.23)	81.78 (63.23)
	95% CI	5487.61, 7293.43	4369.30, 6668.20	6017.33, 9944.93	90.89, 151.13	61.34, 109.03
	p-value (one-sided)				0.109	
Day 90	n	45	29	9		
	Geometric LS Mean (CV%)	6075.93	5678.61	7332.21	107.00 (88.16)	82.87 (88.16)
	95% CI	4824.51, 7651.96	4278.87, 7536.23	4369.24, 12304.50	74.29, 154.10	47.10, 145.77
	p-value (one-sided)					

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.4 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NEQ (mg) Day 5	n	69	31	22		
	Geometric LS Mean (CV%)	11.41	13.54	0.36	84.24 (60.15)	3135.73 (60.15)
	95% CI	9.96, 13.06	11.10, 16.52	0.28, 0.47	66.33, 106.97	2394.67, 4106.11
	p-value (one-sided)				0.079	
Day 90	n	44	29	9		
	Geometric LS Mean (CV%)	10.61	11.18	1.63	94.96 (89.00)	652.14 (89.00)
	95% CI	8.38, 13.44	8.39, 14.88	0.96, 2.75	65.61, 137.45	369.84, 1149.91
	p-value (one-sided)					

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Exhaled CO (ppm)						
Day 5	n	79	41	39		
	LS Mean	2.43	23.12	4.97	-20.69	-2.54
	95% CI	1.06, 3.80	21.23, 25.01	3.03, 6.92	-23.01, -18.37	-4.91, -0.18
	p-value (one-sided)				<0.001	
Day 90	n	79	41	39		
	LS Mean	6.73	20.68	11.27	-13.95	-4.54
	95% CI	5.07, 8.40	18.39, 22.97	8.91, 13.63	-16.76, -11.14	-7.40, -1.68
	p-value (one-sided)				<0.001	

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total 1-OHP (pg/mg creat)						
Day 5	n	69	36	37		
	Geometric LS Mean (CV%)	60.14	125.99	61.60	47.73 (36.72)	97.63 (36.72)
	95% CI	55.16, 65.57	112.03, 141.69	54.79, 69.25	41.28, 55.20	84.39, 112.96
	p-value (one-sided)				<0.001	
Day 90	n	69	36	37		
	Geometric LS Mean (CV%)	110.98	164.02	103.77	67.66 (51.03)	106.95 (51.03)
	95% CI	98.73, 124.75	139.92, 192.26	88.57, 121.58	55.59, 82.35	87.81, 130.26
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NNN (pg/mg creat)						
Day 5	n	71	36	36		
	Geometric LS Mean (CV%)	0.92	6.94	0.23	13.22 (123.61)	402.60 (123.61)
	95% CI	0.72, 1.16	5.05, 9.55	0.16, 0.32	8.95, 19.54	271.49, 597.01
	p-value (one-sided)				<0.001	
Day 90	n	71	36	36		
	Geometric LS Mean (CV%)	0.99	5.73	0.93	17.26 (125.16)	106.18 (125.16)
	95% CI	0.78, 1.25	4.16, 7.91	0.67, 1.29	11.64, 25.58	71.37, 157.96
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
4-ABP (pg/mg creat)						
Day 5	n	71	36	36		
	Geometric LS Mean (CV%)	1.89	9.97	2.16	18.95 (76.92)	87.40 (76.92)
	95% CI	1.60, 2.23	7.95, 12.50	1.72, 2.72	14.37, 25.00	66.25, 115.29
	p-value (one-sided)				<0.001	
Day 90	n	71	36	36		
	Geometric LS Mean (CV%)	3.99	12.76	5.76	31.30 (93.23)	69.29 (93.23)
	95% CI	3.30, 4.82	9.81, 16.58	4.43, 7.50	22.71, 43.14	50.24, 95.54
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
1-NA (pg/mg creat)						
Day 5	n	71	36	36		
	Geometric LS Mean (CV%)	2.72	67.09	3.85	4.05 (95.89)	70.58 (95.89)
	95% CI	2.24, 3.30	51.36, 87.64	2.94, 5.04	2.92, 5.63	50.84, 97.98
	p-value (one-sided)				<0.001	
Day 90	n	71	36	36		
	Geometric LS Mean (CV%)	10.84	67.80	18.11	15.99 (109.20)	59.88 (109.20)
	95% CI	8.78, 13.39	50.57, 90.89	13.49, 24.31	11.16, 22.91	41.78, 85.81
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
2-NA (pg/mg creat)						
Day 5	n	71	36	36		
	Geometric LS Mean (CV%)	2.28	17.66	2.81	12.94 (73.32)	81.35 (73.32)
	95% CI	1.95, 2.67	14.21, 21.94	2.25, 3.50	9.91, 16.89	62.32, 106.18
	p-value (one-sided)				<0.001	
Day 90	n	71	36	36		
	Geometric LS Mean (CV%)	3.59	19.30	6.29	18.62 (77.80)	57.15 (77.80)
	95% CI	3.05, 4.24	15.37, 24.25	5.00, 7.91	14.08, 24.62	43.21, 75.57
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
o-tol (pg/mg creat)						
Day 5	n	71	36	36		
	Geometric LS Mean (CV%)	45.38	95.21	42.78	47.66 (53.99)	106.08 (53.99)
	95% CI	40.24, 51.17	80.46, 112.66	36.16, 50.60	38.78, 58.57	86.38, 130.27
	p-value (one-sided)				<0.001	
Day 90	n	71	36	36		
	Geometric LS Mean (CV%)	47.60	114.50	50.30	41.57 (60.74)	94.63 (60.74)
	95% CI	41.66, 54.38	95.02, 137.97	41.75, 60.59	33.08, 52.23	75.36, 118.82
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CEMA (ng/mg creat)						
Day 5	n	71	36	36		
	Geometric LS Mean (CV%)	14.51	85.87	16.52	16.90 (57.83)	87.85 (57.83)
	95% CI	12.77, 16.49	71.88, 102.58	13.81, 19.75	13.58, 21.02	70.62, 109.28
	p-value (one-sided)				<0.001	
Day 90	n	71	36	36		
	Geometric LS Mean (CV%)	17.85	92.02	30.12	19.40 (128.87)	59.26 (128.87)
	95% CI	14.11, 22.58	66.32, 127.67	21.68, 41.84	12.98, 28.99	39.64, 88.59
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HEMA (pg/mg creat)						
Day 5	n	71	36	36		
	Geometric LS Mean (CV%)	1212.87	3248.51	1462.45	37.34 (58.73)	82.93 (58.73)
	95% CI	1065.17, 1381.05	2713.93, 3888.38	1220.73, 1752.03	29.94, 46.56	66.46, 103.49
	p-value (one-sided)				<0.001	
Day 90	n	71	36	36		
	Geometric LS Mean (CV%)	1594.69	3804.37	2272.84	41.92 (76.39)	70.16 (76.39)
	95% CI	1356.55, 1874.64	3041.05, 4759.29	1814.85, 2846.39	31.84, 55.18	53.25, 92.44
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
B[a]P (fg/mg creat)						
Day 5	n	71	36	36		
	Geometric LS Mean (CV%)	32.84	113.43	28.88	28.95 (65.43)	113.71 (65.43)
	95% CI	28.44, 37.91	93.13, 138.15	23.66, 35.25	22.71, 36.90	88.88, 145.47
	p-value (one-sided)				<0.001	
Day 90	n	71	36	36		
	Geometric LS Mean (CV%)	59.06	122.04	59.58	48.40 (79.13)	99.13 (79.13)
	95% CI	49.95, 69.84	96.94, 153.64	47.20, 75.20	36.45, 64.25	74.34, 132.19
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HMPMA (ng/mg creat)						
Day 5	n	71	36	36		
	Geometric LS Mean (CV%)	100.58	275.99	102.36	36.44 (61.66)	98.27 (61.66)
	95% CI	87.89, 115.10	228.77, 332.96	84.75, 123.62	28.95, 45.88	78.01, 123.77
	p-value (one-sided)				<0.001	
Day 90	n	71	36	36		
	Geometric LS Mean (CV%)	112.38	244.79	122.30	45.91 (72.17)	91.89 (72.17)
	95% CI	96.36, 131.06	197.61, 303.22	98.61, 151.68	35.30, 59.70	70.62, 119.56
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-BMA (pg/mg creat)						
Day 5	n	69	36	36		
	Geometric LS Mean (CV%)	3686.73	3348.08	4156.97	110.11 (58.94)	88.69 (58.94)
	95% CI	3232.07, 4205.34	2795.32, 4010.14	3467.51, 4983.53	88.11, 137.62	70.98, 110.82
	p-value (one-sided)				0.197	
Day 90	n	69	36	36		
	Geometric LS Mean (CV%)	4054.02	3791.19	3573.46	106.93 (85.45)	113.45 (85.45)
	95% CI	3391.41, 4846.08	2968.38, 4842.06	2794.45, 4569.63	79.03, 144.67	83.87, 153.45
	p-value (one-sided)					

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NEQ (mg/g creat)						
Day 5	n	71	36	36		
	Geometric LS Mean (CV%)	7.16	8.20	0.33	87.40 (95.11)	2160.30 (95.11)
	95% CI	5.92, 8.67	6.28, 10.70	0.25, 0.44	63.06, 121.12	1559.02, 2993.48
	p-value (one-sided)				0.208	
Day 90	n	71	36	36		
	Geometric LS Mean (CV%)	7.25	7.42	3.74	97.70 (85.06)	194.15 (85.06)
	95% CI	6.08, 8.65	5.81, 9.48	2.92, 4.78	72.38, 131.87	143.85, 262.03
	p-value (one-sided)					

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
MHBMA (ng)						
Day 5	n	71	36	36		
	Geometric LS Mean (CV%)	184.25	1634.98	245.05	11.27 (97.60)	75.19 (97.60)
	95% CI	151.70, 223.80	1245.92, 2145.52	186.73, 321.58	8.06, 15.75	53.87, 104.94
	p-value (one-sided)				<0.001	
Day 90	n	71	36	36		
	Geometric LS Mean (CV%)	437.87	2070.83	858.24	21.14 (91.05)	51.02 (91.05)
	95% CI	364.04, 526.68	1599.71, 2680.70	662.98, 1111.02	15.38, 29.06	37.17, 70.03
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
3-HPMA (ug) Day 5	n	74	37	37		
	Geometric LS Mean (CV%)	471.30	1094.53	329.48	43.06 (48.76)	143.05 (48.76)
	95% CI	423.25, 524.81	941.55, 1272.37	283.26, 383.24	35.81, 51.78	118.98, 171.98
	p-value (one-sided)				<0.001	
Day 90	n	74	37	37		
	Geometric LS Mean (CV%)	530.64	1035.41	481.60	51.25 (56.63)	110.18 (56.63)
	95% CI	469.32, 599.98	871.84, 1229.67	405.24, 572.34	41.52, 63.26	89.27, 135.99
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-PMA (ng)						
Day 5	n	71	36	36		
	Geometric LS Mean (CV%)	229.52	2118.73	301.30	10.83 (92.24)	76.18 (92.24)
	95% CI	190.61, 276.36	1635.26, 2745.14	232.23, 390.91	7.88, 14.89	55.40, 104.73
	p-value (one-sided)				<0.001	
Day 90	n	71	36	36		
	Geometric LS Mean (CV%)	656.67	2305.33	897.34	28.48 (144.41)	73.18 (144.41)
	95% CI	510.77, 844.24	1623.85, 3272.81	630.93, 1276.24	18.53, 43.78	47.57, 112.58
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total NNAL (ng)						
Day 5	n	73	36	36		
	Geometric LS Mean (CV%)	93.96	227.12	100.72	41.37 (47.07)	93.29 (47.07)
	95% CI	84.62, 104.34	195.93, 263.27	86.81, 116.86	34.54, 49.55	77.84, 111.80
	p-value (one-sided)				<0.001	
Day 90	n	73	36	36		
	Geometric LS Mean (CV%)	92.29	286.67	137.02	32.19 (114.82)	67.36 (114.82)
	95% CI	74.46, 114.39	211.78, 388.02	101.04, 185.80	22.24, 46.60	46.48, 97.62
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total 1-OHP (ng)						
Day 5	n	70	36	37		
	Geometric LS Mean (CV%)	100.96	210.67	102.59	47.92 (41.22)	98.40 (41.22)
	95% CI	91.77, 111.06	184.83, 240.12	90.00, 116.95	40.77, 56.33	83.66, 115.74
	p-value (one-sided)				<0.001	
Day 90	n	70	36	37		
	Geometric LS Mean (CV%)	181.64	258.49	164.33	70.27 (49.18)	110.53 (49.18)
	95% CI	162.39, 203.17	221.65, 301.44	140.90, 191.66	58.12, 84.97	91.34, 133.75
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NNN (ng) Day 5	n	73	36	36		
	Geometric LS Mean (CV%)	1.48	11.38	0.38	13.03 (125.44)	393.50 (125.44)
	95% CI	1.18, 1.87	8.25, 15.69	0.27, 0.53	8.80, 19.30	265.08, 584.13
	p-value (one-sided)				<0.001	
Day 90	n	73	36	36		
	Geometric LS Mean (CV%)	1.61	8.96	1.46	18.00 (125.15)	110.28 (125.15)
	95% CI	1.28, 2.03	6.50, 12.35	1.05, 2.02	12.16, 26.63	74.33, 163.61
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
4-ABP (ng)						
Day 5	n	74	37	37		
	Geometric LS Mean (CV%)	3.18	16.58	3.54	19.18 (75.45)	89.95 (75.45)
	95% CI	2.72, 3.72	13.31, 20.64	2.83, 4.41	14.67, 25.08	68.81, 117.59
	p-value (one-sided)				<0.001	
Day 90	n	74	37	37		
	Geometric LS Mean (CV%)	6.61	20.05	8.70	32.98 (93.88)	75.99 (93.88)
	95% CI	5.49, 7.96	15.47, 25.99	6.70, 11.30	24.01, 45.30	55.33, 104.36
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
1-NA (ng)						
Day 5	n	74	37	37		
	Geometric LS Mean (CV%)	4.45	111.02	6.28	4.01 (93.75)	70.84 (93.75)
	95% CI	3.70, 5.36	85.69, 143.83	4.84, 8.15	2.92, 5.51	51.60, 97.25
	p-value (one-sided)				<0.001	
Day 90	n	74	37	37		
	Geometric LS Mean (CV%)	17.55	107.23	28.38	16.37 (110.23)	61.84 (110.23)
	95% CI	14.26, 21.60	80.17, 143.42	21.19, 38.00	11.46, 23.36	43.32, 88.27
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
2-NA (ng)						
Day 5	n	74	37	37		
	Geometric LS Mean (CV%)	3.70	29.12	4.59	12.72 (70.32)	80.66 (70.32)
	95% CI	3.19, 4.30	23.68, 35.82	3.73, 5.66	9.87, 16.38	62.63, 103.87
	p-value (one-sided)				<0.001	
Day 90	n	74	37	37		
	Geometric LS Mean (CV%)	5.92	30.47	9.70	19.44 (81.37)	61.06 (81.37)
	95% CI	5.01, 7.00	24.14, 38.45	7.68, 12.26	14.63, 25.85	45.94, 81.15
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
o-tol (ng) Day 5	n	74	37	37		
	Geometric LS Mean (CV%)	73.12	157.00	70.11	46.57 (52.27)	104.29 (52.27)
	95% CI	65.21, 81.98	133.69, 184.38	59.67, 82.37	38.25, 56.70	85.71, 126.89
	p-value (one-sided)				<0.001	
Day 90	n	74	37	37		
	Geometric LS Mean (CV%)	76.25	177.69	78.76	42.91 (60.24)	96.82 (60.24)
	95% CI	66.98, 86.80	148.13, 213.16	65.62, 94.53	34.34, 53.62	77.53, 120.89
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CEMA (ug)						
Day 5	n	74	37	37		
	Geometric LS Mean (CV%)	24.42	145.21	27.99	16.81 (60.57)	87.24 (60.57)
	95% CI	21.43, 27.81	121.01, 174.25	23.30, 33.61	13.45, 21.02	69.80, 109.04
	p-value (one-sided)				<0.001	
Day 90	n	74	37	37		
	Geometric LS Mean (CV%)	30.40	146.64	47.90	20.73 (130.73)	63.47 (130.73)
	95% CI	24.09, 38.36	105.89, 203.07	34.55, 66.42	13.92, 30.89	42.61, 94.53
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HEMA (ng) Day 5	n	74	37	37		
	Geometric LS Mean (CV%)	1998.74	5407.56	2431.56	36.96 (57.94)	82.20 (57.94)
	95% CI	1763.02, 2265.97	4537.80, 6444.03	2038.96, 2899.75	29.82, 45.81	66.29, 101.92
	p-value (one-sided)				<0.001	
Day 90	n	74	37	37		
	Geometric LS Mean (CV%)	2632.61	5965.04	3616.04	44.13 (72.03)	72.80 (72.03)
	95% CI	2264.13, 3061.06	4831.74, 7364.15	2926.44, 4468.14	34.10, 57.12	56.22, 94.27
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
B[a]P (pg) Day 5	n	73	36	36		
	Geometric LS Mean (CV%)	55.38	187.67	47.87	29.51 (64.25)	115.69 (64.25)
	95% CI	48.20, 63.63	154.56, 227.86	39.31, 58.29	23.26, 37.44	90.84, 147.34
	p-value (one-sided)				<0.001	
Day 90	n	73	36	36		
	Geometric LS Mean (CV%)	97.55	192.77	95.46	50.60 (76.50)	102.18 (76.50)
	95% CI	83.10, 114.51	154.07, 241.20	76.05, 119.84	38.44, 66.61	77.29, 135.10
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HMPMA (ug)						
Day 5	n	74	37	37		
	Geometric LS Mean (CV%)	167.03	469.82	175.67	35.55 (61.63)	95.08 (61.63)
	95% CI	146.36, 190.62	390.50, 565.26	145.89, 211.51	28.35, 44.58	75.82, 119.25
	p-value (one-sided)				<0.001	
Day 90	n	74	37	37		
	Geometric LS Mean (CV%)	181.83	393.14	199.95	46.25 (68.42)	90.94 (68.42)
	95% CI	157.40, 210.05	321.24, 481.12	163.25, 244.90	36.12, 59.22	71.02, 116.45
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-BMA (ng) Day 5	n	71	36	36		
	Geometric LS Mean (CV%)	6240.81	5629.89	7037.91	110.85 (59.60)	88.67 (59.60)
	95% CI	5475.96, 7112.48	4689.55, 6758.79	5861.23, 8450.83	88.55, 138.76	70.88, 110.93
	p-value (one-sided)				0.183	
Day 90	n	71	36	36		
	Geometric LS Mean (CV%)	6456.54	5977.86	5705.31	108.01 (85.75)	113.17 (85.75)
	95% CI	5414.28, 7699.44	4673.79, 7645.78	4459.50, 7299.15	79.82, 146.14	83.71, 153.00
	p-value (one-sided)					

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.5 Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - FAS Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NEQ (mg)						
Day 5	n	73	37	37		
	Geometric LS Mean (CV%)	11.65	13.84	0.55	84.12 (100.06)	2130.58 (100.06)
	95% CI	9.57, 14.17	10.54, 18.17	0.41, 0.72	60.26, 117.43	1527.16, 2972.42
	p-value (one-sided)				0.154	
Day 90	n	73	37	37		
	Geometric LS Mean (CV%)	11.77	11.80	5.74	99.69 (86.55)	205.11 (86.55)
	95% CI	9.86, 14.03	9.24, 15.07	4.49, 7.33	73.89, 134.49	152.10, 276.57
	p-value (one-sided)					

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
MHBMA (pg/mg creat)						
Day 5	n	64	29	21		
	Geometric LS Mean (CV%)	112.13	907.64	95.60	12.35 (77.34)	117.29 (77.34)
	95% CI	94.27, 133.38	703.51, 1170.99	71.04, 128.64	9.07, 16.83	83.25, 165.24
	p-value (one-sided)				<0.001	
Day 90	n	43	28	9		
	Geometric LS Mean (CV%)	212.93	1145.94	328.66	18.58 (86.10)	64.79 (86.10)
	95% CI	168.13, 269.67	863.22, 1521.26	196.90, 548.58	12.81, 26.94	36.75, 114.21
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
3-HPMA (ng/mg creat)						
Day 5	n	66	29	21		
	Geometric LS Mean (CV%)	276.44	593.00	151.32	46.62 (36.26)	182.68 (36.26)
	95% CI	253.28, 301.72	520.61, 675.46	129.94, 176.22	39.90, 54.47	153.38, 217.57
	p-value (one-sided)				<0.001	
Day 90	n	43	28	9		
	Geometric LS Mean (CV%)	310.61	593.45	210.90	52.34 (53.84)	147.28 (53.84)
	95% CI	265.30, 363.65	490.06, 718.66	149.41, 297.68	40.89, 66.99	100.96, 214.85
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-PMA (pg/mg creat)						
Day 5	n	64	29	21		
	Geometric LS Mean (CV%)	133.23	1057.79	130.84	12.60 (70.33)	101.82 (70.33)
	95% CI	113.57, 156.29	836.85, 1337.06	99.40, 172.22	9.50, 16.70	74.22, 139.70
	p-value (one-sided)				<0.001	
Day 90	n	43	28	9		
	Geometric LS Mean (CV%)	265.27	1184.57	225.64	22.39 (134.93)	117.56 (134.93)
	95% CI	192.98, 364.62	805.51, 1742.03	112.93, 450.84	13.60, 36.86	55.10, 250.79
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
COHb (%)						
Day 5	n	63	29	19		
	Geometric LS Mean (CV%)	2.35	6.33	2.32	37.06 (21.89)	100.90 (21.89)
	95% CI	2.21, 2.48	5.83, 6.86	2.10, 2.57	33.64, 40.82	90.16, 112.91
	p-value (one-sided)				<0.001	
Day 90	n	39	24	6		
	Geometric LS Mean (CV%)	2.59	5.98	2.80	43.28 (31.70)	92.35 (31.70)
	95% CI	2.33, 2.87	5.26, 6.79	2.17, 3.62	36.79, 50.92	70.14, 121.58
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total NNAL (pg/mg creat)						
Day 5	n	66	29	21		
	Geometric LS Mean (CV%)	55.14	123.76	54.77	44.55 (40.78)	100.66 (40.78)
	95% CI	49.99, 60.81	107.06, 143.06	46.21, 64.92	37.44, 53.01	82.82, 122.35
	p-value (one-sided)				<0.001	
Day 90	n	43	28	9		
	Geometric LS Mean (CV%)	41.03	150.26	54.18	27.30 (105.81)	75.73 (105.81)
	95% CI	31.27, 53.82	108.20, 208.67	30.10, 97.50	17.83, 41.80	39.81, 144.03
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Exhaled CO (ppm)						
Day 5	n	75	34	24		
	LS Mean	2.14	21.72	2.00	-19.58	0.15
	95% CI	1.23, 3.06	20.39, 23.06	0.41, 3.59	-21.18, -17.98	-1.67, 1.96
	p-value (one-sided)				<0.001	
Day 90	n	43	29	8		
	LS Mean	4.54	20.68	4.70	-16.15	-0.17
	95% CI	2.68, 6.39	18.46, 22.91	0.41, 9.00	-19.05, -13.25	-4.84, 4.51
	p-value (one-sided)				<0.001	

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total 1-OHP (pg/mg creat)						
Day 5	n	64	29	22		
	Geometric LS Mean (CV%)	60.69	124.88	57.61	48.60 (31.19)	105.36 (31.19)
	95% CI	56.15, 65.61	111.57, 139.78	50.53, 65.67	42.43, 55.68	90.37, 122.82
	p-value (one-sided)				<0.001	
Day 90	n	43	28	9		
	Geometric LS Mean (CV%)	108.74	163.59	94.78	66.47 (50.30)	114.73 (50.30)
	95% CI	93.41, 126.58	136.63, 195.86	68.26, 131.61	52.47, 84.20	79.62, 165.30
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NNN (pg/mg creat)						
Day 5	n	66	29	21		
	Geometric LS Mean (CV%)	0.90	6.14	0.13	14.57 (78.80)	681.27 (78.80)
	95% CI	0.75, 1.07	4.75, 7.94	0.09, 0.18	10.70, 19.84	480.88, 965.16
	p-value (one-sided)				<0.001	
Day 90	n	43	28	9		
	Geometric LS Mean (CV%)	0.90	4.92	0.34	18.27 (87.20)	267.68 (87.20)
	95% CI	0.70, 1.15	3.69, 6.55	0.20, 0.57	12.58, 26.52	152.57, 469.63
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
4-ABP (pg/mg creat)						
Day 5	n	66	29	21		
	Geometric LS Mean (CV%)	1.84	9.28	1.53	19.87 (64.48)	120.36 (64.48)
	95% CI	1.59, 2.14	7.46, 11.55	1.18, 1.98	15.30, 25.80	89.70, 161.50
	p-value (one-sided)				<0.001	
Day 90	n	41	28	9		
	Geometric LS Mean (CV%)	3.18	11.35	3.20	28.02 (92.21)	99.33 (92.21)
	95% CI	2.47, 4.09	8.42, 15.29	1.87, 5.46	19.01, 41.29	55.25, 178.56
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
1-NA (pg/mg creat)						
Day 5	n	66	29	21		
	Geometric LS Mean (CV%)	2.66	62.58	2.27	4.25 (57.63)	116.97 (57.63)
	95% CI	2.32, 3.05	51.34, 76.29	1.80, 2.87	3.35, 5.39	89.56, 152.76
	p-value (one-sided)				<0.001	
Day 90	n	43	28	9		
	Geometric LS Mean (CV%)	8.67	60.06	6.48	14.44 (103.61)	133.90 (103.61)
	95% CI	6.63, 11.34	43.44, 83.01	3.62, 11.58	9.50, 21.93	70.80, 253.21
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
2-NA (pg/mg creat)						
Day 5	n	66	29	21		
	Geometric LS Mean (CV%)	2.22	16.50	2.05	13.44 (53.90)	108.37 (53.90)
	95% CI	1.95, 2.52	13.68, 19.90	1.64, 2.55	10.74, 16.81	84.25, 139.38
	p-value (one-sided)				<0.001	
Day 90	n	43	28	9		
	Geometric LS Mean (CV%)	2.81	17.32	3.37	16.25 (69.00)	83.64 (69.00)
	95% CI	2.31, 3.43	13.67, 21.95	2.19, 5.15	11.97, 22.05	52.48, 133.29
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
o-tol (pg/mg creat)						
Day 5	n	66	29	21		
	Geometric LS Mean (CV%)	44.30	89.26	34.72	49.63 (48.64)	127.59 (48.64)
	95% CI	39.50, 49.68	75.19, 105.97	28.43, 42.40	40.44, 60.90	101.44, 160.47
	p-value (one-sided)				<0.001	
Day 90	n	43	28	9		
	Geometric LS Mean (CV%)	47.00	106.56	41.99	44.11 (68.44)	111.93 (68.44)
	95% CI	38.75, 57.01	84.10, 135.02	27.57, 63.95	32.54, 59.79	70.72, 177.16
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CEMA (ng/mg creat)						
Day 5	n	66	29	21		
	Geometric LS Mean (CV%)	13.83	79.44	13.08	17.41 (42.27)	105.76 (42.27)
	95% CI	12.50, 15.31	68.36, 92.31	10.97, 15.60	14.55, 20.84	86.46, 129.38
	p-value (one-sided)				<0.001	
Day 90	n	43	28	9		
	Geometric LS Mean (CV%)	11.86	82.09	14.46	14.45 (122.58)	82.05 (122.58)
	95% CI	8.80, 15.99	57.10, 118.02	7.55, 27.67	9.04, 23.08	40.38, 166.67
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HEMA (pg/mg creat)						
Day 5	n	66	29	21		
	Geometric LS Mean (CV%)	1149.66	2932.23	1104.24	39.21 (56.15)	104.11 (56.15)
	95% CI	1008.34, 1310.79	2416.47, 3558.07	880.14, 1385.39	31.08, 49.45	80.20, 135.16
	p-value (one-sided)				<0.001	
Day 90	n	43	28	9		
	Geometric LS Mean (CV%)	1397.34	3645.48	1796.05	38.33 (70.62)	77.80 (70.62)
	95% CI	1143.19, 1708.01	2865.17, 4638.28	1167.48, 2763.05	28.02, 52.43	48.56, 124.63
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
B[a]P (fg/mg creat)						
Day 5	n	66	29	21		
	Geometric LS Mean (CV%)	31.90	109.18	21.07	29.22 (55.08)	151.43 (55.08)
	95% CI	27.99, 36.35	90.23, 132.11	16.76, 26.48	23.25, 36.71	115.96, 197.74
	p-value (one-sided)				<0.001	
Day 90	n	41	28	9		
	Geometric LS Mean (CV%)	56.18	125.96	58.83	44.60 (71.57)	95.49 (71.57)
	95% CI	45.47, 69.42	98.59, 160.93	37.85, 91.43	32.14, 61.89	58.31, 156.39
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HMPMA (ng/mg creat)						
Day 5	n	66	29	21		
	Geometric LS Mean (CV%)	94.70	242.97	78.27	38.98 (53.80)	121.00 (53.80)
	95% CI	83.53, 107.37	201.64, 292.76	62.90, 97.39	31.18, 48.72	94.17, 155.46
	p-value (one-sided)				<0.001	
Day 90	n	43	28	9		
	Geometric LS Mean (CV%)	107.75	215.26	105.33	50.06 (65.16)	102.31 (65.16)
	95% CI	89.44, 129.81	171.84, 269.65	70.39, 157.60	37.40, 67.00	65.85, 158.94
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-BMA (pg/mg creat)						
Day 5	n	64	29	21		
	Geometric LS Mean (CV%)	3729.47	3189.18	4608.25	116.94 (62.67)	80.93 (62.67)
	95% CI	3226.12, 4311.36	2576.62, 3947.36	3589.89, 5915.49	90.43, 151.23	60.73, 107.85
	p-value (one-sided)				0.115	
Day 90	n	43	28	9		
	Geometric LS Mean (CV%)	3793.79	3469.41	4301.04	109.35 (92.14)	88.21 (92.14)
	95% CI	2967.27, 4850.53	2578.32, 4668.45	2526.45, 7322.11	74.44, 160.63	49.24, 158.00
	p-value (one-sided)					

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NEQ (mg/g creat)						
Day 5	n	66	29	21		
	Geometric LS Mean (CV%)	7.04	8.01	0.22	87.79 (52.56)	3144.79 (52.56)
	95% CI	6.22, 7.96	6.67, 9.63	0.18, 0.28	70.53, 109.27	2460.29, 4019.74
	p-value (one-sided)				0.120	
Day 90	n	43	28	9		
	Geometric LS Mean (CV%)	6.56	6.78	0.98	96.70 (90.00)	672.00 (90.00)
	95% CI	5.15, 8.34	5.06, 9.10	0.57, 1.65	66.33, 140.97	379.44, 1190.13
	p-value (one-sided)					

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
MHBMA (ng)						
Day 5	n	66	29	21		
	Geometric LS Mean (CV%)	184.19	1502.93	157.30	12.26 (76.72)	117.10 (76.72)
	95% CI	155.52, 218.15	1166.40, 1936.55	117.10, 211.30	9.03, 16.63	83.39, 164.42
	p-value (one-sided)				<0.001	
Day 90	n	45	28	9		
	Geometric LS Mean (CV%)	362.70	1881.53	538.22	19.28 (87.76)	67.39 (87.76)
	95% CI	287.50, 457.56	1411.01, 2508.93	319.12, 907.76	13.28, 27.98	37.91, 119.77
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
3-HPMA (ug) Day 5	n	69	30	22		
	Geometric LS Mean (CV%)	461.46	1010.48	257.68	45.67 (39.77)	179.08 (39.77)
	95% CI	420.43, 506.49	879.20, 1161.37	218.99, 303.19	38.67, 53.93	148.66, 215.74
	p-value (one-sided)				<0.001	
Day 90	n	45	28	9		
	Geometric LS Mean (CV%)	503.18	973.84	339.92	51.67 (51.94)	148.03 (51.94)
	95% CI	433.87, 583.57	809.27, 1171.87	242.76, 475.95	40.78, 65.46	102.69, 213.38
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-PMA (ng)						
Day 5	n	66	29	21		
	Geometric LS Mean (CV%)	223.66	1782.50	218.73	12.55 (72.30)	102.25 (72.30)
	95% CI	190.50, 262.61	1402.70, 2265.15	165.15, 289.69	9.41, 16.72	74.08, 141.14
	p-value (one-sided)				<0.001	
Day 90	n	45	28	9		
	Geometric LS Mean (CV%)	462.09	1956.54	375.73	23.62 (139.07)	122.98 (139.07)
	95% CI	337.17, 633.28	1321.18, 2897.44	185.13, 762.58	14.29, 39.03	56.87, 265.94
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total NNAL (ng)						
Day 5	n	68	29	21		
	Geometric LS Mean (CV%)	90.44	206.62	91.25	43.77 (43.28)	99.12 (43.28)
	95% CI	81.71, 100.11	177.29, 240.81	76.25, 109.19	36.46, 52.54	80.72, 121.71
	p-value (one-sided)				<0.001	
Day 90	n	45	28	9		
	Geometric LS Mean (CV%)	66.94	242.54	87.60	27.60 (113.09)	76.43 (113.09)
	95% CI	50.81, 88.19	172.00, 341.99	47.32, 162.15	17.77, 42.86	39.08, 149.44
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total 1-OHP (ng)						
Day 5	n	65	29	22		
	Geometric LS Mean (CV%)	102.35	210.58	94.79	48.60 (37.93)	107.98 (37.93)
	95% CI	93.30, 112.28	183.89, 241.13	80.85, 111.13	41.28, 57.22	89.70, 129.97
	p-value (one-sided)				<0.001	
Day 90	n	44	28	9		
	Geometric LS Mean (CV%)	179.41	267.68	152.24	67.03 (50.49)	117.85 (50.49)
	95% CI	154.41, 208.47	223.38, 320.77	108.87, 212.86	52.92, 84.89	81.29, 170.85
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NNN (ng) Day 5	n	68	29	21		
	Geometric LS Mean (CV%)	1.45	10.13	0.21	14.33 (82.57)	675.92 (82.57)
	95% CI	1.21, 1.74	7.75, 13.22	0.15, 0.30	10.42, 19.70	471.89, 968.16
	p-value (one-sided)				<0.001	
Day 90	n	45	28	9		
	Geometric LS Mean (CV%)	1.47	7.85	0.53	18.71 (91.14)	278.53 (91.14)
	95% CI	1.15, 1.87	5.84, 10.55	0.31, 0.90	12.81, 27.31	156.31, 496.31
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
4-ABP (ng) Day 5	n	69	30	22		
	Geometric LS Mean (CV%)	3.11	15.69	2.48	19.83 (63.63)	125.58 (63.63)
	95% CI	2.70, 3.59	12.69, 19.40	1.93, 3.18	15.40, 25.54	94.55, 166.79
	p-value (one-sided)				<0.001	
Day 90	n	43	28	9		
	Geometric LS Mean (CV%)	5.44	18.57	4.95	29.28 (95.18)	109.89 (95.18)
	95% CI	4.23, 6.98	13.69, 25.18	2.85, 8.56	19.77, 43.35	60.41, 199.90
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
1-NA (ng) Day 5	n	69	30	22		
	Geometric LS Mean (CV%)	4.34	105.44	3.68	4.12 (56.40)	117.83 (56.40)
	95% CI	3.81, 4.94	87.13, 127.60	2.94, 4.61	3.27, 5.17	91.25, 152.16
	p-value (one-sided)				<0.001	
Day 90	n	45	28	9		
	Geometric LS Mean (CV%)	14.67	98.05	10.10	14.96 (106.13)	145.20 (106.13)
	95% CI	11.26, 19.10	70.56, 136.24	5.57, 18.29	9.82, 22.78	76.11, 277.03
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
2-NA (ng)						
Day 5	n	69	30	22		
	Geometric LS Mean (CV%)	3.59	27.76	3.32	12.92 (51.03)	108.11 (51.03)
	95% CI	3.19, 4.04	23.31, 33.07	2.70, 4.07	10.48, 15.92	85.56, 136.61
	p-value (one-sided)				<0.001	
Day 90	n	45	28	9		
	Geometric LS Mean (CV%)	4.82	28.22	5.31	17.08 (74.80)	90.69 (74.80)
	95% CI	3.93, 5.91	21.92, 36.32	3.36, 8.39	12.37, 23.59	55.22, 148.94
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
o-tol (ng) Day 5	n	69	30	22		
	Geometric LS Mean (CV%)	71.35	150.05	56.60	47.55 (48.08)	126.07 (48.08)
	95% CI	63.86, 79.72	127.07, 177.20	46.62, 68.71	38.99, 58.00	101.00, 157.36
	p-value (one-sided)				<0.001	
Day 90	n	45	28	9		
	Geometric LS Mean (CV%)	75.25	173.07	66.41	43.48 (66.61)	113.31 (66.61)
	95% CI	62.62, 90.44	137.42, 217.98	43.95, 100.35	32.38, 58.38	72.40, 177.33
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CEMA (ug)						
Day 5	n	69	30	22		
	Geometric LS Mean (CV%)	23.49	135.21	22.23	17.37 (46.00)	105.65 (46.00)
	95% CI	21.11, 26.13	115.32, 158.54	18.46, 26.78	14.36, 21.02	85.40, 130.68
	p-value (one-sided)				<0.001	
Day 90	n	45	28	9		
	Geometric LS Mean (CV%)	20.53	134.54	23.63	15.26 (128.16)	86.85 (128.16)
	95% CI	15.22, 27.68	92.62, 195.42	12.10, 46.16	9.46, 24.59	41.97, 179.72
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HEMA (ng)						
Day 5	n	69	30	22		
	Geometric LS Mean (CV%)	1902.39	4945.20	1837.51	38.47 (55.61)	103.53 (55.61)
	95% CI	1675.96, 2159.41	4096.17, 5970.21	1474.50, 2289.87	30.70, 48.20	80.41, 133.30
	p-value (one-sided)				<0.001	
Day 90	n	45	28	9		
	Geometric LS Mean (CV%)	2326.45	5981.99	2941.40	38.89 (70.69)	79.09 (70.69)
	95% CI	1915.09, 2826.18	4700.85, 7612.28	1911.11, 4527.13	28.53, 53.01	49.41, 126.60
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
B[a]P (pg) Day 5	n	68	29	21		
	Geometric LS Mean (CV%)	54.21	183.14	33.95	29.60 (54.13)	159.69 (54.13)
	95% CI	47.80, 61.49	151.84, 220.89	27.05, 42.61	23.67, 37.03	122.73, 207.77
	p-value (one-sided)				<0.001	
Day 90	n	43	28	9		
	Geometric LS Mean (CV%)	94.63	205.25	95.42	46.11 (71.69)	99.18 (71.69)
	95% CI	77.18, 116.04	160.58, 262.34	61.17, 148.83	33.39, 63.66	60.53, 162.50
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HMPMA (ug)						
Day 5	n	69	30	22		
	Geometric LS Mean (CV%)	158.76	421.10	136.02	37.70 (55.50)	116.72 (55.50)
	95% CI	139.98, 180.07	348.91, 508.23	109.19, 169.43	30.11, 47.21	90.76, 150.10
	p-value (one-sided)				<0.001	
Day 90	n	45	28	9		
	Geometric LS Mean (CV%)	173.07	353.04	173.51	49.02 (62.01)	99.75 (62.01)
	95% CI	145.57, 205.77	284.49, 438.12	117.78, 255.60	37.19, 64.62	65.44, 152.03
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-BMA (ng)						
Day 5	n	66	29	21		
	Geometric LS Mean (CV%)	6343.72	5398.70	7759.93	117.50 (63.90)	81.75 (63.90)
	95% CI	5488.31, 7332.45	4343.68, 6709.96	6022.25, 9999.01	90.56, 152.46	61.12, 109.33
	p-value (one-sided)				0.111	
Day 90						
Day 90	n	45	28	9		
	Geometric LS Mean (CV%)	6084.17	5768.34	7312.67	105.48 (88.66)	83.20 (88.66)
	95% CI	4826.25, 7669.95	4322.77, 7697.30	4346.11, 12304.12	72.87, 152.66	47.16, 146.76
	p-value (one-sided)					

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.6 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA using Mixed Model on Day 5/90 Visit - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NEQ (mg)						
Day 5	n	68	30	22		
	Geometric LS Mean (CV%)	11.46	13.56	0.36	84.51 (60.74)	3141.86 (60.74)
	95% CI	9.98, 13.15	11.06, 16.63	0.28, 0.47	66.19, 107.89	2392.46, 4126.00
	p-value (one-sided)				0.087	
Day 90	n	44	28	9		
	Geometric LS Mean (CV%)	10.58	11.18	1.62	94.61 (89.76)	652.38 (89.76)
	95% CI	8.34, 13.42	8.35, 14.97	0.95, 2.75	64.99, 137.73	368.57, 1154.75
	p-value (one-sided)					

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if P-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
MHBMA (pg/mg creat)						
Day 5	n	65	30	21		
	Geometric LS Mean (CV%)	110.96	882.25	94.97	12.58 (76.92)	116.84 (76.92)
	95% CI	93.49, 131.68	687.25, 1132.57	70.67, 127.61	9.27, 17.05	83.12, 164.24
	p-value (one-sided)				<0.001	
Day 90	n	37	29	7		
	Geometric LS Mean (CV%)	218.64	1142.42	232.05	19.14 (80.19)	94.22 (80.19)
	95% CI	172.16, 277.67	877.11, 1487.99	134.96, 398.96	13.35, 27.43	51.81, 171.34
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
3-HPMA (ng/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	278.13	607.68	152.05	45.77 (36.45)	182.92 (36.45)
	95% CI	254.95, 303.43	534.34, 691.09	130.47, 177.19	39.22, 53.41	153.51, 217.97
	p-value (one-sided)				<0.001	
Day 90	n	37	29	7		
	Geometric LS Mean (CV%)	309.35	600.58	207.48	51.51 (54.85)	149.10 (54.85)
	95% CI	260.33, 367.58	495.48, 727.98	139.59, 308.40	39.74, 66.75	96.48, 230.41
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-PMA (pg/mg creat)						
Day 5	n	65	30	21		
	Geometric LS Mean (CV%)	134.11	1065.91	131.05	12.58 (69.68)	102.34 (69.68)
	95% CI	114.63, 156.90	848.45, 1339.09	99.78, 172.13	9.54, 16.58	74.82, 139.97
	p-value (one-sided)				<0.001	
Day 90	n	37	29	7		
	Geometric LS Mean (CV%)	268.15	1200.75	148.92	22.33 (128.49)	180.06 (128.49)
	95% CI	192.43, 373.66	829.48, 1738.19	69.89, 317.30	13.55, 36.79	78.50, 412.98
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
COHb (%) Day 5	n	74	34	23		
	Geometric LS Mean (CV%)	2.33	6.11	2.39	38.14 (26.50)	97.30 (26.50)
	95% CI	2.19, 2.48	5.58, 6.68	2.14, 2.67	34.24, 42.47	86.02, 110.05
	p-value (one-sided)				<0.001	
Day 90	n	41	31	7		
	Geometric LS Mean (CV%)	2.63	5.77	2.30	45.55 (31.62)	114.10 (31.62)
	95% CI	2.38, 2.90	5.16, 6.46	1.82, 2.92	39.24, 52.86	88.32, 147.40
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total NNAL (pg/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	55.44	126.55	55.44	43.81 (40.70)	99.99 (40.70)
	95% CI	50.33, 61.07	109.79, 145.86	46.79, 65.70	36.92, 51.97	82.32, 121.44
	p-value (one-sided)				<0.001	
Day 90	n	37	29	7		
	Geometric LS Mean (CV%)	42.84	152.46	46.65	28.10 (110.39)	91.83 (110.39)
	95% CI	31.72, 57.85	109.17, 212.89	23.56, 92.37	17.89, 44.13	43.38, 194.39
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Exhaled CO (ppm)						
Day 5	n	75	35	24		
	LS Mean	2.20	22.16	2.03	-19.96	0.17
	95% CI	1.25, 3.15	20.79, 23.54	0.37, 3.69	-21.62, -18.31	-1.72, 2.07
	p-value (one-sided)				<0.001	
Day 90	n	41	31	7		
	LS Mean	4.94	19.82	4.27	-14.88	0.67
	95% CI	2.80, 7.09	17.37, 22.27	-0.91, 9.45	-18.14, -11.62	-4.96, 6.30
	p-value (one-sided)				<0.001	

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total 1-OHP (pg/mg creat)						
Day 5	n	65	30	22		
	Geometric LS Mean (CV%)	60.41	125.57	57.56	48.11 (31.01)	104.96 (31.01)
	95% CI	55.96, 65.21	112.49, 140.18	50.53, 65.56	42.11, 54.96	90.17, 122.16
	p-value (one-sided)				<0.001	
Day 90	n	37	29	7		
	Geometric LS Mean (CV%)	113.35	161.62	90.21	70.13 (47.24)	125.66 (47.24)
	95% CI	97.28, 132.07	136.64, 191.18	63.67, 127.80	55.80, 88.14	85.42, 184.83
	p-value (one-sided)				0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NNN (pg/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	0.91	6.44	0.13	14.06 (78.93)	678.32 (78.93)
	95% CI	0.76, 1.08	4.99, 8.29	0.09, 0.19	10.38, 19.06	479.07, 960.44
	p-value (one-sided)				<0.001	
Day 90	n	37	29	7		
	Geometric LS Mean (CV%)	0.89	5.04	0.30	17.58 (91.81)	296.68 (91.81)
	95% CI	0.68, 1.16	3.76, 6.76	0.16, 0.55	11.81, 26.18	153.62, 572.94
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
4-ABP (pg/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	1.86	9.63	1.54	19.31 (64.86)	120.62 (64.86)
	95% CI	1.60, 2.16	7.76, 11.95	1.19, 2.00	14.90, 25.01	89.83, 161.97
	p-value (one-sided)				<0.001	
Day 90	n	37	29	7		
	Geometric LS Mean (CV%)	3.50	11.51	2.50	30.38 (83.62)	140.09 (83.62)
	95% CI	2.73, 4.47	8.76, 15.12	1.42, 4.37	21.02, 43.89	75.75, 259.08
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
1-NA (pg/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	2.67	64.48	2.29	4.15 (57.67)	116.96 (57.67)
	95% CI	2.34, 3.06	53.07, 78.34	1.81, 2.89	3.28, 5.25	89.59, 152.70
	p-value (one-sided)				<0.001	
Day 90	n	37	29	7		
	Geometric LS Mean (CV%)	9.28	60.00	4.53	15.47 (89.90)	204.89 (89.90)
	95% CI	7.16, 12.03	44.95, 80.07	2.50, 8.19	10.48, 22.83	107.08, 392.06
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
2-NA (pg/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	2.24	17.11	2.06	13.12 (54.65)	109.03 (54.65)
	95% CI	1.97, 2.55	14.20, 20.61	1.64, 2.57	10.49, 16.40	84.55, 140.59
	p-value (one-sided)				<0.001	
Day 90	n	37	29	7		
	Geometric LS Mean (CV%)	2.82	17.48	2.63	16.15 (63.17)	107.47 (63.17)
	95% CI	2.32, 3.44	14.06, 21.73	1.68, 4.11	12.05, 21.65	65.88, 175.30
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
o-tol (pg/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	44.82	91.98	34.82	48.72 (49.32)	128.72 (49.32)
	95% CI	39.95, 50.28	77.53, 109.12	28.44, 42.62	39.70, 59.79	102.10, 162.28
	p-value (one-sided)				<0.001	
Day 90	n	37	29	7		
	Geometric LS Mean (CV%)	46.16	108.59	42.35	42.50 (70.24)	109.00 (70.24)
	95% CI	37.29, 57.13	85.39, 138.10	26.06, 68.79	30.73, 58.79	64.06, 185.47
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CEMA (ng/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	13.98	81.15	13.21	17.23 (42.01)	105.84 (42.01)
	95% CI	12.65, 15.45	70.07, 93.98	11.09, 15.74	14.44, 20.55	86.65, 129.27
	p-value (one-sided)				<0.001	
Day 90	n	37	29	7		
	Geometric LS Mean (CV%)	11.66	82.77	10.36	14.09 (117.89)	112.59 (117.89)
	95% CI	8.52, 15.96	58.31, 117.47	5.05, 21.23	8.78, 22.60	51.26, 247.29
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HEMA (pg/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	1160.03	2959.77	1108.66	39.19 (55.70)	104.63 (55.70)
	95% CI	1019.67, 1319.71	2451.31, 3573.68	885.11, 1388.68	31.22, 49.20	80.79, 135.51
	p-value (one-sided)				<0.001	
Day 90	n	37	29	7		
	Geometric LS Mean (CV%)	1374.33	3594.21	1312.91	38.24 (62.93)	104.68 (62.93)
	95% CI	1131.06, 1669.92	2895.74, 4461.16	843.14, 2044.39	28.55, 51.21	64.46, 169.98
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
B[a]P (fg/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	32.09	110.89	21.07	28.94 (54.77)	152.32 (54.77)
	95% CI	28.22, 36.49	92.04, 133.59	16.78, 26.45	23.14, 36.20	116.94, 198.39
	p-value (one-sided)				<0.001	
Day 90	n	37	29	7		
	Geometric LS Mean (CV%)	55.05	123.98	50.05	44.40 (71.00)	109.99 (71.00)
	95% CI	44.30, 68.42	97.60, 157.49	30.63, 81.78	32.05, 61.51	63.95, 189.18
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HMPMA (ng/mg creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	95.32	249.13	78.81	38.26 (53.56)	120.95 (53.56)
	95% CI	84.22, 107.89	207.58, 298.99	63.39, 97.97	30.73, 47.64	94.28, 155.18
	p-value (one-sided)				<0.001	
Day 90	n	37	29	7		
	Geometric LS Mean (CV%)	110.95	218.42	105.32	50.80 (64.07)	105.34 (64.07)
	95% CI	91.06, 135.18	175.39, 272.00	67.21, 165.02	37.76, 68.33	64.31, 172.54
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-BMA (pg/mg creat)						
Day 5	n	65	30	21		
	Geometric LS Mean (CV%)	3745.43	3227.50	4623.62	116.05 (62.06)	81.01 (62.06)
	95% CI	3248.55, 4318.30	2623.07, 3971.21	3609.72, 5922.31	90.29, 149.14	60.97, 107.63
	p-value (one-sided)				0.121	
Day 90	n	37	29	7		
	Geometric LS Mean (CV%)	4050.96	3510.45	5072.07	115.40 (92.79)	79.87 (92.79)
	95% CI	3102.39, 5289.56	2612.95, 4716.22	2774.73, 9271.48	77.25, 172.37	41.12, 155.10
	p-value (one-sided)					

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NEQ (mg/g creat)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	7.06	8.08	0.22	87.33 (52.06)	3137.39 (52.06)
	95% CI	6.25, 7.97	6.76, 9.67	0.18, 0.28	70.49, 108.18	2460.75, 4000.09
	p-value (one-sided)				0.106	
Day 90	n	37	29	7		
	Geometric LS Mean (CV%)	6.77	6.80	0.67	99.48 (87.70)	1002.90 (87.70)
	95% CI	5.24, 8.73	5.11, 9.05	0.37, 1.21	67.74, 146.07	532.18, 1889.93
	p-value (one-sided)					

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
MHBMA (ng)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	181.31	1442.98	155.91	12.56 (76.87)	116.29 (76.87)
	95% CI	153.25, 214.51	1123.53, 1853.26	116.03, 209.49	9.28, 17.01	82.84, 163.26
	p-value (one-sided)				<0.001	
Day 90	n	39	29	7		
	Geometric LS Mean (CV%)	371.12	1845.69	369.67	20.11 (82.46)	100.39 (82.46)
	95% CI	292.93, 470.17	1408.61, 2418.37	212.22, 643.90	13.99, 28.90	54.60, 184.59
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
3-HPMA (ug)						
Day 5	n	70	31	22		
	Geometric LS Mean (CV%)	461.90	1023.21	257.50	45.14 (39.63)	179.38 (39.63)
	95% CI	421.33, 506.38	892.87, 1172.57	218.98, 302.81	38.33, 53.17	149.05, 215.86
	p-value (one-sided)				<0.001	
Day 90	n	39	29	7		
	Geometric LS Mean (CV%)	498.39	966.56	328.08	51.56 (52.32)	151.91 (52.32)
	95% CI	424.53, 585.10	803.98, 1162.02	224.01, 480.50	40.34, 65.91	100.25, 230.19
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-PMA (ng)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	223.78	1773.28	217.73	12.62 (71.62)	102.78 (71.62)
	95% CI	191.09, 262.05	1404.10, 2239.53	164.76, 287.72	9.52, 16.72	74.69, 141.42
	p-value (one-sided)				<0.001	
Day 90						
Day 90	n	39	29	7		
	Geometric LS Mean (CV%)	468.30	1944.77	239.64	24.08 (132.64)	195.42 (132.64)
	95% CI	337.15, 650.45	1334.04, 2835.11	110.63, 519.07	14.57, 39.80	84.06, 454.29
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total NNAL (ng)						
Day 5	n	69	30	21		
	Geometric LS Mean (CV%)	90.31	209.49	91.63	43.11 (43.12)	98.56 (43.12)
	95% CI	81.70, 99.83	180.36, 243.32	76.62, 109.58	36.03, 51.58	80.35, 120.88
	p-value (one-sided)				<0.001	
Day 90	n	39	29	7		
	Geometric LS Mean (CV%)	69.25	241.44	73.13	28.68 (117.11)	94.70 (117.11)
	95% CI	51.14, 93.77	170.57, 341.73	35.91, 148.88	18.04, 45.58	43.57, 205.81
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total 1-OHP (ng)						
Day 5	n	66	30	22		
	Geometric LS Mean (CV%)	101.23	209.34	94.13	48.36 (37.61)	107.54 (37.61)
	95% CI	92.44, 110.85	183.47, 238.85	80.42, 110.17	41.22, 56.72	89.58, 129.11
	p-value (one-sided)				<0.001	
Day 90	n	38	29	7		
	Geometric LS Mean (CV%)	185.58	260.29	143.49	71.30 (48.29)	129.34 (48.29)
	95% CI	159.09, 216.48	219.30, 308.94	100.22, 205.42	56.53, 89.93	87.02, 192.24
	p-value (one-sided)				0.002	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NNN (ng)						
Day 5	n	69	30	21		
	Geometric LS Mean (CV%)	1.46	10.50	0.22	13.92 (82.33)	674.45 (82.33)
	95% CI	1.22, 1.75	8.08, 13.63	0.15, 0.30	10.18, 19.03	471.67, 964.39
	p-value (one-sided)				<0.001	
Day 90	n	39	29	7		
	Geometric LS Mean (CV%)	1.44	7.89	0.46	18.23 (95.39)	313.18 (95.39)
	95% CI	1.10, 1.88	5.84, 10.67	0.24, 0.86	12.20, 27.25	159.87, 613.49
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
4-ABP (ng)						
Day 5	n	70	31	22		
	Geometric LS Mean (CV%)	3.13	16.05	2.48	19.48 (63.42)	125.86 (63.42)
	95% CI	2.71, 3.60	13.03, 19.75	1.94, 3.18	15.18, 24.99	94.90, 166.92
	p-value (one-sided)				<0.001	
Day 90	n	39	29	7		
	Geometric LS Mean (CV%)	5.92	18.47	3.79	32.07 (88.46)	156.43 (88.46)
	95% CI	4.62, 7.60	13.89, 24.56	2.11, 6.80	21.95, 46.86	82.63, 296.12
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
1-NA (ng)						
Day 5	n	70	31	22		
	Geometric LS Mean (CV%)	4.35	106.92	3.69	4.07 (55.99)	117.94 (55.99)
	95% CI	3.83, 4.94	88.75, 128.80	2.95, 4.61	3.25, 5.10	91.53, 151.98
	p-value (one-sided)				<0.001	
Day 90	n	39	29	7		
	Geometric LS Mean (CV%)	15.70	96.28	6.97	16.31 (95.01)	225.35 (95.01)
	95% CI	12.09, 20.40	71.28, 130.03	3.76, 12.92	10.93, 24.35	115.04, 441.41
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
2-NA (ng)						
Day 5	n	70	31	22		
	Geometric LS Mean (CV%)	3.62	28.33	3.33	12.78 (51.14)	108.89 (51.14)
	95% CI	3.22, 4.07	23.85, 33.66	2.71, 4.09	10.40, 15.72	86.17, 137.59
	p-value (one-sided)				<0.001	
Day 90						
Day 90	n	39	29	7		
	Geometric LS Mean (CV%)	4.85	27.99	4.04	17.32 (70.69)	120.03 (70.69)
	95% CI	3.93, 5.97	22.04, 35.54	2.47, 6.60	12.60, 23.81	70.34, 204.81
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
o-tol (ng)						
Day 5	n	70	31	22		
	Geometric LS Mean (CV%)	72.02	152.19	56.60	47.32 (48.14)	127.23 (48.14)
	95% CI	64.52, 80.39	129.22, 179.23	46.62, 68.72	38.89, 57.58	101.96, 158.76
	p-value (one-sided)				<0.001	
Day 90	n	39	29	7		
	Geometric LS Mean (CV%)	73.97	173.61	66.12	42.61 (68.60)	111.88 (68.60)
	95% CI	60.35, 90.66	137.27, 219.56	41.06, 106.48	31.11, 58.34	66.59, 187.94
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CEMA (ug)						
Day 5	n	70	31	22		
	Geometric LS Mean (CV%)	23.56	136.87	22.29	17.21 (45.68)	105.70 (45.68)
	95% CI	21.21, 26.16	117.17, 159.88	18.53, 26.81	14.28, 20.74	85.60, 130.53
	p-value (one-sided)				<0.001	
Day 90	n	39	29	7		
	Geometric LS Mean (CV%)	20.21	132.99	16.18	15.20 (123.33)	124.93 (123.33)
	95% CI	14.76, 27.66	92.75, 190.68	7.71, 33.91	9.39, 24.57	55.78, 279.79
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HEMA (ng)						
Day 5	n	70	31	22		
	Geometric LS Mean (CV%)	1908.19	4934.43	1833.48	38.67 (55.19)	104.07 (55.19)
	95% CI	1684.39, 2161.72	4106.13, 5929.82	1473.51, 2281.40	30.99, 48.25	81.01, 133.71
	p-value (one-sided)				<0.001	
Day 90	n	39	29	7		
	Geometric LS Mean (CV%)	2292.94	5785.10	2078.04	39.64 (63.18)	110.34 (63.18)
	95% CI	1897.45, 2770.87	4658.22, 7184.59	1333.89, 3237.35	29.68, 52.92	68.02, 178.98
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
B[a]P (pg) Day 5	n	69	30	21		
	Geometric LS Mean (CV%)	54.24	183.37	33.80	29.58 (53.63)	160.48 (53.63)
	95% CI	47.93, 61.37	152.79, 220.07	26.99, 42.32	23.77, 36.81	123.78, 208.04
	p-value (one-sided)				<0.001	
Day 90	n	39	29	7		
	Geometric LS Mean (CV%)	92.39	199.26	79.78	46.37 (72.02)	115.81 (72.02)
	95% CI	74.71, 114.26	156.43, 253.82	48.47, 131.29	33.51, 64.15	67.02, 200.11
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
HMPMA (ug)						
Day 5	n	70	31	22		
	Geometric LS Mean (CV%)	158.79	427.05	136.16	37.18 (55.13)	116.62 (55.13)
	95% CI	140.26, 179.76	355.41, 513.12	109.46, 169.38	29.82, 46.36	90.86, 149.67
	p-value (one-sided)				<0.001	
Day 90						
Day 90	n	39	29	7		
	Geometric LS Mean (CV%)	176.75	351.79	168.25	50.24 (60.94)	105.06 (60.94)
	95% CI	147.15, 212.31	285.12, 434.04	109.33, 258.89	37.96, 66.49	65.62, 168.18
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-BMA (ng)						
Day 5	n	67	30	21		
	Geometric LS Mean (CV%)	6326.41	5397.72	7735.76	117.21 (63.23)	81.78 (63.23)
	95% CI	5487.61, 7293.43	4369.30, 6668.20	6017.33, 9944.93	90.89, 151.13	61.34, 109.03
	p-value (one-sided)				0.109	
Day 90						
Day 90	n	39	29	7		
	Geometric LS Mean (CV%)	6420.23	5769.37	8317.37	111.28 (89.45)	77.19 (89.45)
	95% CI	4993.87, 8253.99	4326.33, 7693.73	4618.67, 14978.04	75.67, 163.64	40.52, 147.02
	p-value (one-sided)					

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.

**Table 15.2.3.7 Sensitivity Analysis of Additional Biomarkers of Exposure versus mCC and SA on Day 5/90 Visit - Compliant Population**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
NEQ (mg) Day 5	n	69	31	22		
	Geometric LS Mean (CV%)	11.41	13.54	0.36	84.24 (60.15)	3135.73 (60.15)
	95% CI	9.96, 13.06	11.10, 16.52	0.28, 0.47	66.33, 106.97	2394.67, 4106.11
	p-value (one-sided)				0.079	
Day 90	n	38	29	7		
	Geometric LS Mean (CV%)	10.80	11.02	1.09	97.94 (86.86)	992.07 (86.86)
	95% CI	8.40, 13.88	8.31, 14.62	0.61, 1.94	66.93, 143.31	529.35, 1859.25
	p-value (one-sided)					

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value is for the one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant, in all biomarkers except for Total NNAL.



15.2.4 Secondary Endpoints Summary Tables

**Table 15.2.4.1.1 Descriptive Statistics of Blood COHb (%) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		34		23	
	Missing, n (%)	1 (1.3)		1 (2.9)		1 (4.2)	
	Geometric Mean (CV%)	6.66 (29.163)		6.16 (28.377)		6.54 (28.455)	
	95% CI of Geometric Mean	6.23, 7.13		5.59, 6.80		5.79, 7.38	
	Median	6.85		6.25		6.80	
	Q25, Q75	5.60, 8.10		5.60, 7.30		5.40, 8.10	
	Min, Max	2.2, 12.6		2.8, 9.7		3.4, 9.5	
	Mean (SD)	6.92 (1.859)		6.38 (1.586)		6.77 (1.730)	
	95% CI of Mean	6.49, 7.36		5.82, 6.94		6.02, 7.52	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1 Descriptive Statistics of Blood COHb (%) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Geometric Mean (CV%)	2.84 (31.339)		5.97 (28.944)		2.95 (34.371)	
	95% CI of Geometric Mean	2.64, 3.05		5.40, 6.60		2.55, 3.42	
	Median	2.70	-61.38	5.90	-2.56	2.70	-56.00
	Q25, Q75	2.40, 2.90	-66.67, -51.79	5.40, 7.20	-11.25, 0.00	2.50, 3.10	-65.85, -51.72
	Min, Max	1.8, 10.8	-78.6, 0.0	2.3, 9.1	-20.7, 33.8	1.8, 8.1	-72.8, 0.0
	Mean (SD)	3.01 (1.395)	-54.09 (20.291)	6.18 (1.521)	-2.50 (11.599)	3.15 (1.402)	-51.09 (22.557)
	95% CI of Mean	2.69, 3.34	-58.79, -49.38	5.65, 6.72	-6.55, 1.56	2.54, 3.76	-60.85, -41.33

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1 Descriptive Statistics of Blood COHb (%) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Geometric Mean (CV%)	2.62 (29.207)		6.07 (31.089)		2.79 (40.447)	
	95% CI of Geometric Mean	2.44, 2.80		5.45, 6.75		2.36, 3.31	
	Median	2.50	-63.43	5.95	-4.14	2.60	-57.41
	Q25, Q75	2.30, 2.70	-69.70, -54.00	5.60, 7.30	-11.34, 0.00	2.30, 2.80	-70.53, -50.94
	Min, Max	1.6, 10.8	-84.1, 0.0	2.3, 10.6	-25.0, 62.7	1.5, 8.1	-74.7, 0.0
	Mean (SD)	2.76 (1.254)	-57.54 (19.109)	6.32 (1.685)	0.19 (20.508)	3.04 (1.511)	-53.09 (23.402)
	95% CI of Mean	2.47, 3.06	-61.97, -53.11	5.73, 6.91	-6.97, 7.35	2.38, 3.70	-63.22, -42.97

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1 Descriptive Statistics of Blood COHb (%) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Geometric Mean (CV%)	2.46 (23.229)		6.21 (27.183)		2.39 (38.557)	
	95% CI of Geometric Mean	2.32, 2.59		5.66, 6.83		2.03, 2.81	
	Median	2.40	-63.98	6.50	0.00	2.40	-66.04
	Q25, Q75	2.20, 2.70	-71.21, -58.00	5.40, 7.20	-6.85, 15.00	1.90, 2.60	-71.79, -60.29
	Min, Max	1.4, 5.9	-78.2, 9.1	2.8, 10.8	-32.2, 37.3	1.3, 8.1	-75.3, 0.0
	Mean (SD)	2.53 (0.685)	-60.86 (15.839)	6.41 (1.554)	2.39 (18.251)	2.59 (1.369)	-60.75 (18.952)
	95% CI of Mean	2.36, 2.69	-64.53, -57.18	5.87, 6.96	-3.98, 8.77	1.99, 3.18	-68.95, -52.55

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1 Descriptive Statistics of Blood COHb (%) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Geometric Mean (CV%)	2.44 (18.040)		6.17 (29.632)		2.29 (34.377)	
	95% CI of Geometric Mean	2.34, 2.55		5.57, 6.83		1.98, 2.65	
	Median	2.40	-63.75	6.35	0.00	2.20	-67.95
	Q25, Q75	2.30, 2.60	-71.08, -55.56	5.90, 7.30	-6.67, 8.62	1.90, 2.50	-72.41, -60.94
	Min, Max	1.5, 5.9	-81.0, 4.5	2.6, 9.2	-23.2, 33.9	1.5, 8.1	-76.8, 0.0
	Mean (SD)	2.48 (0.524)	-61.09 (15.228)	6.40 (1.596)	0.84 (12.736)	2.46 (1.298)	-62.37 (18.050)
	95% CI of Mean	2.36, 2.61	-64.62, -57.55	5.84, 6.96	-3.61, 5.29	1.89, 3.03	-70.18, -54.56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1 Descriptive Statistics of Blood COHb (%) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, Within 15 Min Prior To Smoking	n	67	67	31	31		
	Missing, n (%)	8 (10.7)	8 (10.7)	4 (11.4)	4 (11.4)		
	Geometric Mean (CV%)	2.38 (16.932)		4.22 (23.001)			
	95% CI of Geometric Mean	2.28, 2.49		3.88, 4.59			
	Median	2.40	-64.41	4.30	-33.33		
	Q25, Q75	2.20, 2.60	-70.13, -55.36	3.60, 4.90	-42.47, -23.08		
	Min, Max	1.5, 4.9	-82.6, -9.1	2.5, 6.7	-52.2, -5.9		
	Mean (SD)	2.42 (0.448)	-61.94 (13.114)	4.33 (0.972)	-31.92 (12.304)		
	95% CI of Mean	2.30, 2.53	-65.14, -58.73	3.96, 4.69	-36.43, -27.40		

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1 Descriptive Statistics of Blood COHb (%) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 08:00 - 09:30	n					21	21
	Missing, n (%)					3 (12.5)	3 (12.5)
	Geometric Mean (CV%)					2.22 (20.780)	
	95% CI of Geometric Mean					2.01, 2.44	
	Median					2.10	-67.37
	Q25, Q75					1.90, 2.60	-73.33, -58.73
	Min, Max					1.5, 3.1	-77.9, -16.7
	Mean (SD)					2.26 (0.469)	-64.09 (13.636)
	95% CI of Mean					2.04, 2.48	-70.30, -57.88

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1 Descriptive Statistics of Blood COHb (%) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 12:00 - 13:30	n	65	65	30	30	19	19
	Missing, n (%)	10 (13.3)	10 (13.3)	5 (14.3)	5 (14.3)	5 (20.8)	5 (20.8)
	Geometric Mean (CV%)	2.49 (14.337)		5.86 (30.041)		2.32 (15.470)	
	95% CI of Geometric Mean	2.40, 2.58		5.25, 6.55		2.15, 2.50	
	Median	2.50	-63.24	6.00	-6.01	2.40	-65.85
	Q25, Q75	2.30, 2.70	-69.05, -55.00	5.20, 7.00	-13.73, 5.00	2.10, 2.60	-71.43, -55.88
	Min, Max	1.7, 3.8	-81.7, 9.1	2.6, 9.3	-39.7, 36.8	1.6, 3.0	-79.2, -27.8
	Mean (SD)	2.51 (0.362)	-60.48 (14.013)	6.09 (1.607)	-5.45 (15.869)	2.34 (0.344)	-62.57 (12.598)
	95% CI of Mean	2.42, 2.61	-63.95, -57.00	5.49, 6.70	-11.38, 0.48	2.17, 2.51	-68.65, -56.49

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1 Descriptive Statistics of Blood COHb (%) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 16:00 - 17:30	n	66	66	29	29	18	18
	Missing, n (%)	9 (12.0)	9 (12.0)	6 (17.1)	6 (17.1)	6 (25.0)	6 (25.0)
	Geometric Mean (CV%)	2.39 (18.884)		6.14 (25.378)		2.22 (12.984)	
	95% CI of Geometric Mean	2.28, 2.51		5.58, 6.76		2.07, 2.37	
	Median	2.40	-63.96	6.10	-6.06	2.25	-68.00
	Q25, Q75	2.20, 2.60	-69.70, -57.38	5.30, 7.60	-13.40, 8.33	2.00, 2.40	-73.68, -60.34
	Min, Max	1.4, 5.2	-83.7, 4.5	3.5, 9.3	-40.3, 36.8	1.7, 2.7	-76.8, -44.1
	Mean (SD)	2.44 (0.497)	-61.90 (13.755)	6.32 (1.538)	-2.88 (16.064)	2.23 (0.283)	-66.26 (8.202)
	95% CI of Mean	2.31, 2.56	-65.28, -58.51	5.73, 6.91	-9.00, 3.23	2.09, 2.38	-70.34, -62.18

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1 Descriptive Statistics of Blood COHb (%) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 20:00 - 21:30	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Geometric Mean (CV%)	2.37 (24.420)		6.07 (27.534)		2.42 (35.466)	
	95% CI of Geometric Mean	2.23, 2.51		5.52, 6.68		2.08, 2.81	
	Median	2.40	-65.17	6.25	-1.28	2.20	-66.67
	Q25, Q75	2.20, 2.60	-72.53, -52.73	5.60, 7.30	-8.33, 9.09	2.10, 2.50	-70.45, -60.38
	Min, Max	0.8, 5.9	-89.7, 0.0	2.8, 9.7	-21.1, 44.9	1.6, 8.1	-75.8, 0.0
	Mean (SD)	2.43 (0.633)	-61.67 (16.578)	6.28 (1.540)	-0.55 (14.128)	2.60 (1.365)	-60.02 (19.127)
	95% CI of Mean	2.28, 2.59	-65.51, -57.82	5.73, 6.82	-5.48, 4.39	2.01, 3.20	-68.30, -51.75

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1 Descriptive Statistics of Blood COHb (%) - PP Set****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34		13	
	Geometric Mean (CV%)	6.45 (34.011)		6.21 (28.196)		6.50 (28.063)	
	95% CI of Geometric Mean	5.80, 7.18		5.64, 6.85		5.50, 7.68	
	Median	6.60		6.35		6.60	
	Q25, Q75	5.30, 7.90		5.70, 7.30		5.60, 7.70	
	Min, Max	2.2, 12.6		2.8, 9.7		3.4, 9.5	
	Mean (SD)	6.79 (2.159)		6.43 (1.571)		6.72 (1.707)	
	95% CI of Mean	6.09, 7.48		5.87, 6.98		5.68, 7.75	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1 Descriptive Statistics of Blood COHb (%) - PP Set****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	40	34	34	13	13
	Geometric Mean (CV%)	2.80 (38.803)		6.13 (34.149)		2.76 (35.472)	
	95% CI of Geometric Mean	2.48, 3.17		5.46, 6.89		2.24, 3.41	
	Median	2.70	-54.36	6.15	0.00	2.40	-57.41
	Q25, Q75	2.20, 3.50	-71.63, -31.81	5.00, 8.00	-17.24, 10.45	2.30, 3.30	-67.24, -54.74
	Min, Max	1.5, 7.3	-83.3, 22.7	2.4, 10.6	-31.8, 71.0	1.7, 5.6	-75.0, 64.7
	Mean (SD)	3.02 (1.271)	-49.97 (27.201)	6.45 (1.969)	0.97 (22.635)	2.93 (1.126)	-50.99 (36.353)
	95% CI of Mean	2.60, 3.43	-58.67, -41.26	5.76, 7.14	-6.93, 8.87	2.25, 3.62	-72.97, -29.02

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1 Descriptive Statistics of Blood COHb (%) - PP Set****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35		12	
	Geometric Mean (CV%)	6.47 (33.894)		6.18 (27.978)		5.89 (29.792)	
	95% CI of Geometric Mean	5.81, 7.21		5.62, 6.80		4.89, 7.09	
	Median	6.60		6.30		6.10	
	Q25, Q75	5.50, 7.80		5.60, 7.30		5.35, 7.15	
	Min, Max	2.2, 12.6		2.8, 9.7		3.4, 9.2	
	Mean (SD)	6.81 (2.149)		6.39 (1.564)		6.11 (1.651)	
	95% CI of Mean	6.11, 7.51		5.85, 6.93		5.05, 7.16	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1 Descriptive Statistics of Blood COHb (%) - PP Set****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	35	35	12	12
	Geometric Mean (CV%)	2.91 (41.628)		5.49 (39.299)		2.76 (64.752)	
	95% CI of Geometric Mean	2.55, 3.31		4.82, 6.26		1.89, 4.03	
	Median	2.70	-56.60	6.20	-4.17	2.05	-57.84
	Q25, Q75	2.10, 3.40	-69.61, -34.09	4.50, 7.20	-20.31, 12.90	1.80, 4.75	-74.45, -26.68
	Min, Max	1.7, 9.2	-84.1, 36.4	2.4, 12.7	-64.2, 54.9	1.5, 7.7	-78.3, 126.5
	Mean (SD)	3.18 (1.598)	-48.85 (28.336)	5.87 (2.089)	-7.23 (25.912)	3.30 (2.250)	-37.75 (58.749)
	95% CI of Mean	2.65, 3.70	-58.04, -39.66	5.14, 6.59	-16.14, 1.67	1.87, 4.73	-75.08, -0.42

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1 Descriptive Statistics of Blood COHb (%) - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Geometric Mean (CV%)	6.49 (32.154)		6.23 (24.338)		5.79 (33.474)	
	95% CI of Geometric Mean	5.91, 7.12		5.71, 6.80		4.50, 7.45	
	Median	6.60		6.30		6.40	
	Q25, Q75	5.50, 7.80		5.65, 7.25		5.40, 6.80	
	Min, Max	2.2, 12.6		2.8, 9.5		3.4, 9.2	
	Mean (SD)	6.79 (2.040)		6.40 (1.391)		6.06 (1.826)	
	95% CI of Mean	6.19, 7.40		5.89, 6.90		4.65, 7.46	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1 Descriptive Statistics of Blood COHb (%) - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	Geometric Mean (CV%)	2.66 (35.163)		5.62 (33.240)		2.84 (52.689)	
	95% CI of Geometric Mean	2.40, 2.94		5.00, 6.32		1.93, 4.16	
	Median	2.50	-57.97	5.60	-7.15	2.50	-53.70
	Q25, Q75	2.20, 3.10	-68.49, -45.45	4.85, 6.90	-18.75, 9.40	2.10, 3.00	-72.00, -41.67
	Min, Max	1.6, 6.4	-84.9, 45.5	2.4, 10.3	-64.2, 37.3	1.5, 7.7	-77.9, 126.5
	Mean (SD)	2.83 (1.143)	-55.30 (21.368)	5.90 (1.811)	-6.88 (22.143)	3.21 (1.948)	-35.24 (64.000)
	95% CI of Mean	2.49, 3.17	-61.58, -49.03	5.24, 6.56	-14.87, 1.11	1.71, 4.71	-84.44, 13.96

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Baseline	n	45	29	20	14	14	9
	Missing, n (%)	1 (2.2)	0	0	1 (6.7)	1 (6.7)	0
	Geometric Mean (CV%)	6.41 (29.982)	7.08 (27.185)	6.37 (29.321)	5.89 (27.349)	6.17 (29.552)	7.16 (25.480)
	95% CI of Geometric Mean	5.86, 7.01	6.39, 7.84	5.56, 7.29	5.04, 6.88	5.21, 7.29	5.90, 8.68
	Median	6.80	7.20	6.40	6.10	6.35	7.50
	Q25, Q75	5.50, 7.80	6.20, 8.30	5.90, 7.30	5.10, 6.80	5.40, 7.80	5.80, 9.20
	Min, Max	2.2, 11.1	3.8, 12.6	2.9, 9.7	2.8, 8.2	3.4, 8.8	5.0, 9.5
	Mean (SD)	6.66 (1.777)	7.32 (1.942)	6.60 (1.703)	6.06 (1.404)	6.39 (1.650)	7.36 (1.782)
	95% CI of Mean	6.12, 7.20	6.58, 8.07	5.80, 7.40	5.25, 6.88	5.44, 7.35	5.98, 8.73

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 1	n	45	29	20	14	14	9
	Missing, n (%)	1 (2.2)	0	0	1 (6.7)	1 (6.7)	0
	Geometric Mean (CV%)	2.78 (26.111)	2.94 (38.545)	6.04 (29.901)	5.87 (28.579)	2.82 (33.964)	3.17 (35.785)
	95% CI of Geometric Mean	2.56, 3.00	2.55, 3.39	5.27, 6.94	4.99, 6.90	2.33, 3.42	2.42, 4.14
	Median	2.70	2.80	6.25	5.70	2.70	2.70
	Q25, Q75	2.40, 2.90	2.40, 3.00	5.35, 7.20	5.40, 6.40	2.50, 2.80	2.50, 3.40
	Min, Max	1.8, 8.5	1.8, 10.8	2.3, 8.8	2.8, 9.1	1.8, 8.1	2.2, 5.8
	Mean (SD)	2.89 (1.083)	3.20 (1.781)	6.26 (1.517)	6.07 (1.578)	3.01 (1.498)	3.36 (1.296)
	95% CI of Mean	2.56, 3.22	2.52, 3.89	5.55, 6.97	5.16, 6.99	2.14, 3.88	2.35, 4.36

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 1	n	45	29	20	14	14	9
	Missing, n (%)	1 (2.2)	0	0	1 (6.7)	1 (6.7)	0
	Median	-58.57	-63.86	-3.76	-0.79	-55.32	-61.43
	Q25, Q75	-65.56, -50.00	-67.90, -54.55	-11.32, 0.00	-8.54, 9.80	-64.94, -51.72	-69.33, -54.67
	Min, Max	-77.5, 0.0	-78.6, 0.0	-20.7, 23.1	-15.2, 33.8	-69.2, 0.0	-72.8, 0.0
	Mean (SD)	-53.68 (19.461)	-54.71 (21.854)	-4.53 (10.596)	0.41 (12.729)	-51.79 (18.451)	-50.00 (29.050)
	95% CI of Mean	-59.54, -47.83	-63.03, -46.40	-9.49, 0.44	-6.95, 7.76	-62.45, -41.13	-72.34, -27.67

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 2	n	45	29	20	14	14	9
	Missing, n (%)	1 (2.2)	0	0	1 (6.7)	1 (6.7)	0
	Geometric Mean (CV%)	2.52 (18.367)	2.78 (40.959)	5.98 (30.259)	6.20 (33.326)	2.58 (39.822)	3.16 (40.155)
	95% CI of Geometric Mean	2.38, 2.66	2.39, 3.23	5.20, 6.87	5.14, 7.48	2.06, 3.23	2.34, 4.26
	Median	2.50	2.40	5.80	6.10	2.55	2.70
	Q25, Q75	2.30, 2.70	2.20, 2.90	5.45, 7.25	5.60, 7.40	2.20, 2.80	2.40, 4.60
	Min, Max	1.6, 5.9	2.0, 10.8	2.3, 8.8	2.8, 10.6	1.5, 8.1	2.0, 5.8
	Mean (SD)	2.56 (0.594)	3.07 (1.840)	6.20 (1.554)	6.49 (1.903)	2.81 (1.582)	3.39 (1.410)
	95% CI of Mean	2.38, 2.75	2.36, 3.77	5.47, 6.93	5.38, 7.59	1.90, 3.73	2.30, 4.48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 2	n	45	29	20	14	14	9
	Missing, n (%)	1 (2.2)	0	0	1 (6.7)	1 (6.7)	0
	Median	-62.00	-66.13	-5.73	0.00	-57.02	-62.86
	Q25, Q75	-68.24, -54.00	-69.70, -55.56	-13.56, -2.79	-7.50, 15.87	-71.19, -54.41	-68.00, -50.00
	Min, Max	-79.2, 0.0	-84.1, 0.0	-25.0, 43.6	-20.0, 62.7	-72.7, 0.0	-74.7, 0.0
	Mean (SD)	-58.23 (16.503)	-56.48 (22.850)	-5.08 (15.306)	7.73 (24.924)	-55.07 (19.787)	-50.01 (29.195)
	95% CI of Mean	-63.19, -53.26	-65.17, -47.78	-12.25, 2.08	-6.67, 22.13	-66.50, -43.64	-72.46, -27.57

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 3	n	45	29	20	14	14	9
	Missing, n (%)	1 (2.2)	0	0	1 (6.7)	1 (6.7)	0
	Geometric Mean (CV%)	2.50 (21.715)	2.38 (25.523)	6.18 (21.856)	6.26 (34.537)	2.44 (43.567)	2.30 (31.804)
	95% CI of Geometric Mean	2.34, 2.67	2.16, 2.63	5.59, 6.85	5.15, 7.60	1.91, 3.11	1.81, 2.93
	Median	2.40	2.40	6.35	6.90	2.35	2.40
	Q25, Q75	2.10, 2.70	2.20, 2.70	5.55, 7.10	5.20, 7.30	1.90, 2.70	1.90, 2.40
	Min, Max	1.9, 5.9	1.4, 5.0	3.1, 8.4	2.8, 10.8	1.3, 8.1	1.6, 4.5
	Mean (SD)	2.57 (0.704)	2.46 (0.662)	6.31 (1.193)	6.56 (2.003)	2.70 (1.635)	2.41 (0.866)
	95% CI of Mean	2.35, 2.79	2.20, 2.72	5.75, 6.87	5.40, 7.73	1.75, 3.65	1.74, 3.08

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 3	n	45	29	20	14	14	9
	Missing, n (%)	1 (2.2)	0	0	1 (6.7)	1 (6.7)	0
	Median	-62.07	-67.61	-3.80	6.02	-63.29	-68.00
	Q25, Q75	-68.24, -52.73	-72.84, -61.29	-13.15, 5.91	0.00, 28.00	-68.29, -58.73	-72.41, -65.33
	Min, Max	-78.2, 9.1	-77.8, -23.7	-32.2, 35.9	-29.7, 37.3	-75.3, 0.0	-74.7, -51.1
	Mean (SD)	-58.36 (17.509)	-64.73 (12.113)	-1.63 (16.128)	8.15 (20.120)	-56.61 (22.959)	-67.19 (7.380)
	95% CI of Mean	-63.63, -53.10	-69.35, -60.12	-9.19, 5.92	-3.48, 19.77	-69.87, -43.35	-72.86, -61.51

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 4	n	45	29	20	14	14	9
	Missing, n (%)	1 (2.2)	0	0	1 (6.7)	1 (6.7)	0
	Geometric Mean (CV%)	2.52 (19.176)	2.33 (15.263)	6.26 (29.454)	6.04 (30.906)	2.41 (40.966)	2.12 (21.258)
	95% CI of Geometric Mean	2.37, 2.67	2.19, 2.47	5.47, 7.17	5.07, 7.20	1.91, 3.03	1.80, 2.50
	Median	2.50	2.40	6.40	6.20	2.30	2.10
	Q25, Q75	2.30, 2.70	2.20, 2.50	6.00, 7.35	5.50, 7.00	1.90, 2.60	2.00, 2.40
	Min, Max	1.5, 5.9	1.5, 3.0	2.6, 9.1	2.8, 9.2	1.5, 8.1	1.6, 3.1
	Mean (SD)	2.57 (0.604)	2.36 (0.338)	6.48 (1.556)	6.28 (1.704)	2.65 (1.619)	2.17 (0.467)
	95% CI of Mean	2.38, 2.75	2.22, 2.49	5.75, 7.21	5.29, 7.27	1.71, 3.59	1.80, 2.53

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 4	n	45	29	20	14	14	9
	Missing, n (%)	1 (2.2)	0	0	1 (6.7)	1 (6.7)	0
	Median	-61.02	-68.42	-2.89	0.98	-64.92	-70.00
	Q25, Q75	-69.41, -52.00	-74.07, -61.02	-10.73, 4.95	-1.52, 12.20	-68.29, -59.26	-72.83, -68.00
	Min, Max	-79.3, 4.5	-81.0, -34.2	-23.2, 33.9	-23.2, 24.0	-75.3, 0.0	-76.8, -60.0
	Mean (SD)	-58.16 (16.987)	-65.63 (10.767)	-0.83 (13.618)	3.23 (11.412)	-57.47 (21.704)	-70.00 (4.787)
	95% CI of Mean	-63.26, -53.05	-69.73, -61.53	-7.21, 5.54	-3.36, 9.83	-70.01, -44.93	-73.69, -66.32

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 5, Within 15 Min Prior To Smoking	n	43	24	19	12		
	Missing, n (%)	3 (6.5)	5 (17.2)	1 (5.0)	3 (20.0)		
	Geometric Mean (CV%)	2.33 (14.260)	2.48 (20.648)	4.15 (21.309)	4.33 (26.281)		
	95% CI of Geometric Mean	2.22, 2.44	2.27, 2.71	3.75, 4.60	3.67, 5.11		
	Median	2.30	2.45	4.40	4.20		
	Q25, Q75	2.20, 2.50	2.25, 2.70	3.80, 4.80	3.50, 5.20		
	Min, Max	1.5, 3.1	1.6, 4.9	2.5, 5.8	3.0, 6.7		
	Mean (SD)	2.35 (0.321)	2.53 (0.605)	4.24 (0.823)	4.47 (1.197)		
	95% CI of Mean	2.25, 2.45	2.27, 2.79	3.84, 4.64	3.70, 5.23		

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 5	n	43	24	19	12		
	Missing, n (%)	3 (6.5)	5 (17.2)	1 (5.0)	3 (20.0)		
	Median	-63.93	-64.92	-33.33	-33.68		
	Q25, Q75	-70.24, -55.00	-69.46, -61.31	-42.62, -23.08	-36.81, -22.13		
	Min, Max	-82.6, -9.1	-80.2, -39.5	-52.2, -13.8	-46.4, -5.9		
	Mean (SD)	-61.19 (14.648)	-63.27 (9.940)	-33.22 (12.195)	-29.85 (12.724)		
	95% CI of Mean	-65.70, -56.68	-67.47, -59.07	-39.11, -27.34	-37.94, -21.76		

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 5, 08:00 - 09:30	n					12	9
	Missing, n (%)					3 (20.0)	0
	Geometric Mean (CV%)					2.29 (18.212)	2.12 (24.239)
	95% CI of Geometric Mean					2.04, 2.57	1.76, 2.56
	Median					2.25	2.10
	Q25, Q75					1.95, 2.70	1.80, 2.40
	Min, Max					1.8, 3.0	1.5, 3.1
	Mean (SD)					2.33 (0.425)	2.18 (0.536)
	95% CI of Mean					2.05, 2.60	1.76, 2.59

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 5	n					12	9
	Missing, n (%)					3 (20.0)	0
	Median					-60.50	-68.48
	Q25, Q75					-71.88, -57.12	-73.33, -67.37
	Min, Max					-76.6, -16.7	-77.9, -65.4
	Mean (SD)					-59.61 (16.556)	-70.07 (4.200)
	95% CI of Mean					-70.13, -49.08	-73.30, -66.83

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 5, 12:00 - 13:30	n	40	25	19	11	12	7
	Missing, n (%)	6 (13.0)	4 (13.8)	1 (5.0)	4 (26.7)	3 (20.0)	2 (22.2)
	Geometric Mean (CV%)	2.47 (12.902)	2.52 (16.585)	5.58 (32.565)	6.39 (24.116)	2.32 (17.880)	2.32 (11.553)
	95% CI of Geometric Mean	2.36, 2.58	2.35, 2.70	4.79, 6.51	5.44, 7.50	2.07, 2.60	2.08, 2.58
	Median	2.50	2.40	6.00	6.00	2.40	2.40
	Q25, Q75	2.30, 2.70	2.20, 2.90	4.80, 7.00	5.30, 7.90	2.15, 2.60	2.00, 2.60
	Min, Max	1.7, 3.0	2.1, 3.8	2.6, 8.4	4.4, 9.3	1.6, 3.0	2.0, 2.6
	Mean (SD)	2.49 (0.304)	2.56 (0.442)	5.83 (1.592)	6.55 (1.598)	2.35 (0.395)	2.33 (0.263)
	95% CI of Mean	2.39, 2.59	2.37, 2.74	5.05, 6.60	5.48, 7.63	2.09, 2.61	2.08, 2.58

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 5	n	40	25	19	11	12	7
	Missing, n (%)	6 (13.0)	4 (13.8)	1 (5.0)	4 (26.7)	3 (20.0)	2 (22.2)
	Median	-61.96	-63.95	-12.33	-3.66	-59.54	-71.43
	Q25, Q75	-70.58, -52.83	-67.12, -61.29	-20.51, 1.39	-6.67, 15.79	-67.54, -55.14	-72.63, -68.00
	Min, Max	-78.4, 9.1	-81.7, -34.1	-39.7, 12.2	-13.7, 36.8	-79.2, -27.8	-73.7, -60.0
	Mean (SD)	-59.02 (15.882)	-62.80 (10.226)	-10.63 (13.963)	3.49 (15.509)	-58.39 (14.006)	-69.74 (4.647)
	95% CI of Mean	-64.11, -53.94	-67.02, -58.57	-17.36, -3.89	-6.93, 13.91	-67.29, -49.48	-74.04, -65.43

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 5, 16:00 - 17:30	n	41	25	17	12	11	7
	Missing, n (%)	5 (10.9)	4 (13.8)	3 (15.0)	3 (20.0)	4 (26.7)	2 (22.2)
	Geometric Mean (CV%)	2.34 (15.861)	2.49 (22.826)	6.07 (28.279)	6.24 (21.812)	2.17 (15.407)	2.29 (7.739)
	95% CI of Geometric Mean	2.22, 2.46	2.27, 2.74	5.26, 7.01	5.44, 7.16	1.95, 2.41	2.13, 2.47
	Median	2.40	2.50	6.10	6.00	2.10	2.40
	Q25, Q75	2.20, 2.60	2.30, 2.80	5.40, 7.70	5.30, 6.90	1.90, 2.60	2.20, 2.40
	Min, Max	1.4, 3.0	1.6, 5.2	3.5, 8.7	4.7, 9.3	1.7, 2.7	2.0, 2.5
	Mean (SD)	2.36 (0.336)	2.56 (0.674)	6.28 (1.616)	6.38 (1.489)	2.19 (0.337)	2.30 (0.174)
	95% CI of Mean	2.25, 2.47	2.28, 2.84	5.45, 7.12	5.43, 7.33	1.96, 2.42	2.13, 2.47

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 5	n	41	25	17	12	11	7
	Missing, n (%)	5 (10.9)	4 (13.8)	3 (15.0)	3 (20.0)	4 (26.7)	2 (22.2)
	Median	-63.64	-64.79	-6.45	-0.32	-64.06	-68.57
	Q25, Q75	-68.83, -56.67	-71.60, -58.18	-10.96, 5.56	-14.36, 10.75	-71.19, -60.29	-73.91, -68.00
	Min, Max	-83.7, 4.5	-77.0, -34.1	-40.3, 20.7	-19.7, 36.8	-76.1, -44.1	-76.8, -60.0
	Mean (SD)	-61.35 (15.036)	-62.80 (11.585)	-5.59 (15.325)	0.95 (16.966)	-63.97 (8.998)	-69.86 (5.562)
	95% CI of Mean	-66.10, -56.60	-67.59, -58.01	-13.48, 2.29	-9.83, 11.74	-70.02, -57.92	-75.01, -64.71

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 5, 20:00 - 21:30	n	45	29	20	14	14	9
	Missing, n (%)	1 (2.2)	0	0	1 (6.7)	1 (6.7)	0
	Geometric Mean (CV%)	2.41 (27.033)	2.30 (19.919)	6.20 (24.674)	5.90 (32.011)	2.49 (37.265)	2.31 (34.207)
	95% CI of Geometric Mean	2.22, 2.61	2.13, 2.49	5.53, 6.95	4.92, 7.07	2.02, 3.07	1.78, 2.99
	Median	2.40	2.40	6.65	5.80	2.20	2.30
	Q25, Q75	2.20, 2.60	2.20, 2.50	5.75, 7.30	5.00, 7.20	2.10, 2.60	2.10, 2.40
	Min, Max	0.8, 5.9	1.2, 3.0	3.3, 8.6	2.8, 9.7	1.9, 8.1	1.6, 5.0
	Mean (SD)	2.49 (0.742)	2.34 (0.406)	6.36 (1.358)	6.16 (1.817)	2.71 (1.580)	2.44 (1.012)
	95% CI of Mean	2.27, 2.72	2.18, 2.50	5.72, 7.00	5.10, 7.21	1.79, 3.62	1.66, 3.23

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 5	n	45	29	20	14	14	9
	Missing, n (%)	1 (2.2)	0	0	1 (6.7)	1 (6.7)	0
	Median	-64.29	-68.49	-4.06	0.00	-63.85	-69.23
	Q25, Q75	-72.06, -50.00	-72.84, -61.29	-10.83, 4.51	-8.00, 11.25	-69.51, -60.38	-72.41, -68.00
	Min, Max	-89.7, 0.0	-80.2, -34.2	-21.1, 44.9	-19.3, 18.3	-75.3, 0.0	-75.8, -45.7
	Mean (SD)	-58.80 (19.087)	-66.11 (10.508)	-1.53 (15.853)	0.85 (11.651)	-55.70 (22.667)	-66.74 (9.363)
	95% CI of Mean	-64.54, -53.06	-70.11, -62.11	-8.95, 5.89	-5.88, 7.59	-68.79, -42.61	-73.94, -59.54

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=28)	Females (N=19)	Males (N=19)	Females (N=13)	Males (N=7)	Females (N=2)
Baseline	n	28	19	19	13	7	2
	Geometric Mean (CV%)	6.27 (32.749)	6.82 (31.427)	6.51 (20.834)	5.85 (28.430)	5.22 (29.308)	8.31 (14.522)
	95% CI of Geometric Mean	5.54, 7.11	5.88, 7.92	5.89, 7.19	4.94, 6.93	4.00, 6.82	2.26, 30.42
	Median	6.70	6.60	6.60	5.90	5.60	8.35
	Q25, Q75	5.40, 7.50	5.50, 8.10	6.00, 7.30	5.10, 6.80	3.60, 6.60	7.50, 9.20
	Min, Max	2.2, 11.1	3.8, 12.6	3.9, 9.5	2.8, 8.2	3.4, 6.8	7.5, 9.2
	Mean (SD)	6.56 (1.893)	7.14 (2.248)	6.64 (1.328)	6.05 (1.459)	5.40 (1.396)	8.35 (1.203)
	95% CI of Mean	5.82, 7.30	6.05, 8.23	5.99, 7.28	5.16, 6.93	4.10, 6.70	-2.46, 19.16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=28)	Females (N=19)	Males (N=19)	Females (N=13)	Males (N=7)	Females (N=2)
Day 90	n	28	19	19	13	7	2
	Geometric Mean (CV%)	2.59 (36.110)	2.76 (34.371)	5.42 (34.402)	5.93 (32.039)	3.03 (59.339)	2.24 (9.464)
	95% CI of Geometric Mean	2.26, 2.97	2.34, 3.24	4.61, 6.37	4.91, 7.17	1.82, 5.05	0.96, 5.25
	Median	2.55	2.40	5.20	6.10	2.60	2.25
	Q25, Q75	1.95, 3.15	2.30, 3.10	4.50, 7.00	4.90, 6.80	2.10, 5.00	2.10, 2.40
	Min, Max	1.6, 6.3	1.7, 6.4	2.4, 9.2	3.3, 10.3	1.5, 7.7	2.1, 2.4
	Mean (SD)	2.76 (1.114)	2.93 (1.208)	5.69 (1.757)	6.20 (1.918)	3.49 (2.157)	2.25 (0.213)
	95% CI of Mean	2.32, 3.20	2.34, 3.51	4.84, 6.55	5.04, 7.36	1.49, 5.49	0.34, 4.16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.1 Descriptive Statistics of Blood COHb (%) by Sex - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=28)	Females (N=19)	Males (N=19)	Females (N=13)	Males (N=7)	Females (N=2)
%Change from baseline to Day 90	n	28	19	19	13	7	2
	Median	-60.72	-56.86	-8.16	-3.92	-53.13	-72.96
	Q25, Q75	-68.85, -42.32	-68.49, -50.79	-22.73, 0.00	-9.33, 22.00	-60.61, -10.71	-73.91, -72.00
	Min, Max	-80.0, 45.5	-84.9, -20.0	-64.2, 15.4	-31.6, 37.3	-77.9, 126.5	-73.9, -72.0
	Mean (SD)	-54.06 (24.983)	-57.14 (14.988)	-13.82 (20.804)	3.27 (20.725)	-24.47 (69.653)	-72.96 (1.353)
	95% CI of Mean	-63.75, -44.37	-64.37, -49.91	-23.85, -3.79	-9.26, 15.80	-88.89, 39.95	-85.12, -60.80

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
Baseline	n	42	32	20	14	13	10
	Missing, n (%)	1 (2.3)	0	0	1 (6.7)	0	1 (9.1)
	Geometric Mean (CV%)	6.24 (31.503)	7.26 (23.500)	5.92 (25.920)	6.53 (31.638)	6.20 (23.231)	7.01 (34.208)
	95% CI of Geometric Mean	5.67, 6.88	6.67, 7.90	5.25, 6.67	5.46, 7.81	5.39, 7.12	5.52, 8.90
	Median	6.40	7.40	6.15	6.70	6.40	7.80
	Q25, Q75	5.30, 8.10	6.20, 8.10	5.15, 7.00	5.90, 8.00	5.40, 7.50	5.80, 9.20
	Min, Max	2.2, 10.4	4.8, 12.6	2.9, 9.0	2.8, 9.7	3.6, 8.2	3.4, 9.5
	Mean (SD)	6.51 (1.808)	7.46 (1.814)	6.09 (1.401)	6.79 (1.790)	6.34 (1.329)	7.33 (2.084)
	95% CI of Mean	5.95, 7.08	6.80, 8.12	5.43, 6.75	5.75, 7.83	5.53, 7.15	5.83, 8.83

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
Day 1	n	42	32	20	14	13	10
	Missing, n (%)	1 (2.3)	0	0	1 (6.7)	0	1 (9.1)
	Geometric Mean (CV%)	2.75 (24.335)	2.96 (38.938)	5.72 (27.593)	6.35 (30.675)	2.60 (9.550)	3.48 (48.154)
	95% CI of Geometric Mean	2.54, 2.97	2.58, 3.40	5.03, 6.50	5.34, 7.56	2.45, 2.76	2.50, 4.82
	Median	2.70	2.75	5.70	6.55	2.70	3.20
	Q25, Q75	2.40, 3.00	2.40, 2.90	5.30, 6.50	5.60, 7.50	2.40, 2.80	2.50, 5.20
	Min, Max	1.8, 8.5	1.8, 10.8	2.3, 8.8	2.8, 9.1	2.2, 3.1	1.8, 8.1
	Mean (SD)	2.85 (1.017)	3.23 (1.769)	5.90 (1.363)	6.59 (1.688)	2.62 (0.248)	3.84 (1.944)
	95% CI of Mean	2.53, 3.17	2.59, 3.87	5.25, 6.54	5.61, 7.57	2.46, 2.77	2.44, 5.24

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
%Change from baseline to Day 1	n	42	32	20	14	13	10
	Missing, n (%)	1 (2.3)	0	0	1 (6.7)	0	1 (9.1)
	Median	-56.75	-63.76	-2.56	-2.89	-56.00	-57.49
	Q25, Q75	-66.23, -50.00	-68.78, -53.21	-12.26, 7.36	-8.54, 0.00	-64.94, -54.41	-65.91, 0.00
	Min, Max	-73.6, 0.0	-78.6, 0.0	-20.7, 23.1	-15.2, 33.8	-69.3, -25.0	-72.8, 0.0
	Mean (SD)	-53.29 (18.340)	-55.14 (22.862)	-2.72 (11.905)	-2.18 (11.585)	-56.81 (11.327)	-43.66 (31.049)
	95% CI of Mean	-59.01, -47.57	-63.38, -46.89	-8.29, 2.86	-8.88, 4.51	-63.66, -49.96	-65.87, -21.44

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
Day 2	n	42	32	20	14	13	10
	Missing, n (%)	1 (2.3)	0	0	1 (6.7)	0	1 (9.1)
	Geometric Mean (CV%)	2.47 (14.633)	2.83 (40.800)	5.67 (26.372)	6.69 (35.457)	2.41 (16.258)	3.39 (54.846)
	95% CI of Geometric Mean	2.35, 2.59	2.45, 3.26	5.01, 6.40	5.48, 8.17	2.18, 2.66	2.34, 4.89
	Median	2.50	2.45	5.70	7.30	2.50	2.75
	Q25, Q75	2.20, 2.70	2.30, 2.70	5.45, 6.50	5.90, 8.20	2.20, 2.60	2.40, 5.20
	Min, Max	1.6, 3.2	2.0, 10.8	2.3, 8.3	2.8, 10.6	1.7, 3.1	1.5, 8.1
	Mean (SD)	2.49 (0.349)	3.11 (1.821)	5.83 (1.243)	7.02 (2.010)	2.44 (0.378)	3.82 (2.048)
	95% CI of Mean	2.38, 2.61	2.45, 3.77	5.24, 6.41	5.86, 8.19	2.21, 2.67	2.35, 5.29

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
%Change from baseline to Day 2	n	42	32	20	14	13	10
	Missing, n (%)	1 (2.3)	0	0	1 (6.7)	0	1 (9.1)
	Median	-62.03	-65.94	-5.73	0.00	-60.00	-56.51
	Q25, Q75	-67.86, -54.00	-70.12, -55.14	-16.10, -2.80	-6.45, 8.93	-68.00, -56.25	-70.53, 0.00
	Min, Max	-79.2, -4.5	-84.1, 0.0	-25.0, 62.7	-20.0, 55.9	-72.7, -27.8	-74.7, 0.0
	Mean (SD)	-58.19 (15.191)	-56.69 (23.524)	-2.37 (21.739)	3.85 (18.773)	-59.70 (11.950)	-44.50 (31.674)
	95% CI of Mean	-62.93, -53.45	-65.18, -48.20	-12.55, 7.81	-7.00, 14.69	-66.93, -52.47	-67.16, -21.84

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
Day 3	n	42	32	20	14	13	10
	Missing, n (%)	1 (2.3)	0	0	1 (6.7)	0	1 (9.1)
	Geometric Mean (CV%)	2.56 (16.700)	2.33 (29.292)	6.01 (21.914)	6.51 (33.824)	2.27 (18.814)	2.54 (57.342)
	95% CI of Geometric Mean	2.42, 2.70	2.10, 2.59	5.43, 6.66	5.38, 7.88	2.02, 2.55	1.73, 3.73
	Median	2.50	2.25	6.35	7.05	2.30	2.40
	Q25, Q75	2.30, 2.80	2.05, 2.50	5.35, 6.95	5.60, 7.80	1.90, 2.60	1.60, 2.60
	Min, Max	1.9, 4.8	1.4, 5.9	3.1, 8.6	2.8, 10.8	1.8, 3.3	1.3, 8.1
	Mean (SD)	2.59 (0.486)	2.44 (0.883)	6.14 (1.179)	6.81 (1.951)	2.31 (0.449)	2.95 (2.013)
	95% CI of Mean	2.44, 2.75	2.11, 2.76	5.58, 6.69	5.68, 7.95	2.03, 2.58	1.51, 4.39

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
%Change from baseline to Day 3	n	42	32	20	14	13	10
	Missing, n (%)	1 (2.3)	0	0	1 (6.7)	0	1 (9.1)
	Median	-60.70	-69.71	0.99	0.00	-66.04	-67.28
	Q25, Q75	-65.71, -50.94	-73.88, -63.85	-9.88, 21.57	-4.84, 4.55	-68.00, -60.34	-72.73, -58.73
	Min, Max	-78.2, 9.1	-77.8, 0.0	-32.2, 37.3	-23.7, 31.7	-75.3, -8.3	-74.7, 0.0
	Mean (SD)	-56.91 (15.812)	-66.04 (14.534)	3.58 (20.703)	0.69 (14.624)	-61.26 (16.697)	-60.08 (22.481)
	95% CI of Mean	-61.84, -51.98	-71.28, -60.79	-6.11, 13.28	-7.76, 9.14	-71.36, -51.17	-76.16, -43.99

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
Day 4	n	42	32	20	14	13	10
	Missing, n (%)	1 (2.3)	0	0	1 (6.7)	0	1 (9.1)
	Geometric Mean (CV%)	2.56 (10.517)	2.30 (23.587)	6.02 (28.212)	6.39 (32.331)	2.23 (15.246)	2.38 (52.053)
	95% CI of Geometric Mean	2.47, 2.65	2.11, 2.50	5.28, 6.85	5.32, 7.67	2.03, 2.45	1.67, 3.38
	Median	2.50	2.30	6.20	6.50	2.10	2.30
	Q25, Q75	2.40, 2.70	2.15, 2.45	5.80, 6.95	5.90, 7.80	2.00, 2.50	1.60, 2.50
	Min, Max	2.1, 3.3	1.5, 5.9	2.6, 9.1	2.8, 9.2	1.8, 3.0	1.5, 8.1
	Mean (SD)	2.57 (0.275)	2.37 (0.723)	6.22 (1.472)	6.66 (1.781)	2.25 (0.353)	2.73 (1.952)
	95% CI of Mean	2.48, 2.66	2.10, 2.63	5.52, 6.91	5.62, 7.69	2.04, 2.47	1.33, 4.13

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
%Change from baseline to Day 4	n	42	32	20	14	13	10
	Missing, n (%)	1 (2.3)	0	0	1 (6.7)	0	1 (9.1)
	Median	-60.15	-69.71	-2.04	0.00	-66.04	-69.54
	Q25, Q75	-66.13, -51.72	-74.90, -62.68	-6.07, 7.64	-11.34, 10.00	-68.29, -60.94	-72.73, -67.37
	Min, Max	-74.5, 4.5	-81.0, 0.0	-11.8, 33.9	-23.2, 14.7	-75.3, -16.7	-76.8, 0.0
	Mean (SD)	-57.05 (14.655)	-66.38 (14.528)	2.37 (12.785)	-1.35 (12.810)	-62.27 (14.573)	-62.51 (22.653)
	95% CI of Mean	-61.62, -52.48	-71.62, -61.13	-3.62, 8.36	-8.75, 6.05	-71.08, -53.46	-78.72, -46.30

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
Day 5, Within 15 Min Prior To Smoking	n	42	25	20	11		
	Missing, n (%)	1 (2.3)	7 (21.9)	0	4 (26.7)		
	Geometric Mean (CV%)	2.45 (13.518)	2.26 (20.827)	4.02 (22.291)	4.62 (22.328)		
	95% CI of Geometric Mean	2.35, 2.57	2.07, 2.47	3.62, 4.46	3.98, 5.36		
	Median	2.50	2.20	4.15	4.70		
	Q25, Q75	2.30, 2.70	2.10, 2.40	3.55, 4.55	4.20, 5.30		
	Min, Max	1.6, 3.1	1.5, 4.9	2.5, 6.7	3.0, 6.4		
	Mean (SD)	2.48 (0.322)	2.32 (0.598)	4.11 (0.919)	4.72 (0.984)		
	95% CI of Mean	2.37, 2.58	2.06, 2.57	3.68, 4.54	4.05, 5.38		

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
%Change from baseline to Day 5	n	42	25	20	11		
	Missing, n (%)	1 (2.3)	7 (21.9)	0	4 (26.7)		
	Median	-62.81	-68.57	-31.82	-35.37		
	Q25, Q75	-68.57, -54.00	-73.75, -63.93	-42.39, -21.74	-46.43, -27.50		
	Min, Max	-82.6, -9.1	-80.8, -50.0	-52.2, -10.5	-50.5, -5.9		
	Mean (SD)	-58.49 (14.372)	-67.72 (8.033)	-31.17 (11.846)	-33.27 (13.581)		
	95% CI of Mean	-62.98, -54.01	-71.04, -64.40	-36.72, -25.62	-42.40, -24.14		

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
Day 5, 08:00 - 09:30	n					12	9
	Missing, n (%)					1 (7.7)	2 (18.2)
	Geometric Mean (CV%)					2.21 (19.399)	2.22 (23.750)
	95% CI of Geometric Mean					1.95, 2.50	1.85, 2.67
	Median					2.05	2.20
	Q25, Q75					1.95, 2.65	1.90, 2.60
	Min, Max					1.7, 3.0	1.5, 3.1
	Mean (SD)					2.25 (0.447)	2.28 (0.524)
	95% CI of Mean					1.96, 2.54	1.87, 2.69

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
%Change from baseline to Day 5	n					12	9
	Missing, n (%)					1 (7.7)	2 (18.2)
	Median					-65.93	-68.00
	Q25, Q75					-71.67, -57.38	-74.14, -65.38
	Min, Max					-76.6, -16.7	-77.9, -44.1
	Mean (SD)					-62.23 (15.932)	-66.57 (10.186)
	95% CI of Mean					-72.36, -52.10	-74.40, -58.73

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
Day 5, 12:00 - 13:30	n	41	24	20	10	13	6
	Missing, n (%)	2 (4.7)	8 (25.0)	0	5 (33.3)	0	5 (45.5)
	Geometric Mean (CV%)	2.50 (14.453)	2.47 (14.416)	5.46 (30.734)	6.77 (23.454)	2.25 (17.432)	2.46 (8.393)
	95% CI of Geometric Mean	2.38, 2.62	2.32, 2.63	4.74, 6.29	5.73, 7.99	2.03, 2.51	2.25, 2.69
	Median	2.50	2.45	5.90	7.35	2.30	2.55
	Q25, Q75	2.30, 2.80	2.20, 2.70	4.85, 6.55	5.30, 7.90	2.00, 2.40	2.40, 2.60
	Min, Max	1.7, 3.1	2.1, 3.8	2.6, 9.0	4.8, 9.3	1.6, 3.0	2.1, 2.6
	Mean (SD)	2.52 (0.350)	2.50 (0.389)	5.68 (1.502)	6.93 (1.545)	2.28 (0.387)	2.47 (0.197)
	95% CI of Mean	2.41, 2.64	2.33, 2.66	4.97, 6.38	5.82, 8.04	2.05, 2.52	2.26, 2.68

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
%Change from baseline to Day 5	n	41	24	20	10	13	6
	Missing, n (%)	2 (4.7)	8 (25.0)	0	5 (33.3)	0	5 (45.5)
	Median	-61.73	-64.92	-9.72	-4.21	-65.63	-69.87
	Q25, Q75	-67.21, -52.83	-70.63, -60.75	-13.59, 5.69	-19.59, 5.00	-69.49, -55.88	-72.63, -58.73
	Min, Max	-78.4, 9.1	-81.7, -43.8	-39.7, 18.0	-26.3, 36.8	-79.2, -27.8	-73.7, -38.2
	Mean (SD)	-57.98 (15.910)	-64.73 (8.728)	-6.60 (14.945)	-3.16 (18.197)	-61.98 (12.606)	-63.84 (13.680)
	95% CI of Mean	-63.01, -52.96	-68.42, -61.04	-13.60, 0.40	-16.18, 9.87	-69.61, -54.36	-78.20, -49.48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
Day 5, 16:00 - 17:30	n	38	28	18	11	11	7
	Missing, n (%)	5 (11.6)	4 (12.5)	2 (10.0)	4 (26.7)	2 (15.4)	4 (36.4)
	Geometric Mean (CV%)	2.41 (15.131)	2.38 (23.390)	5.87 (20.441)	6.60 (31.707)	2.17 (14.220)	2.29 (11.002)
	95% CI of Geometric Mean	2.28, 2.53	2.17, 2.61	5.31, 6.50	5.36, 8.14	1.97, 2.39	2.06, 2.54
	Median	2.45	2.40	6.00	7.60	2.20	2.40
	Q25, Q75	2.30, 2.60	2.10, 2.60	5.40, 6.40	5.30, 8.70	1.90, 2.40	2.10, 2.50
	Min, Max	1.5, 3.3	1.4, 5.2	3.5, 8.3	3.7, 9.3	1.7, 2.7	1.9, 2.6
	Mean (SD)	2.43 (0.346)	2.45 (0.655)	5.98 (1.145)	6.88 (1.961)	2.19 (0.309)	2.30 (0.245)
	95% CI of Mean	2.31, 2.55	2.19, 2.71	5.41, 6.56	5.56, 8.20	1.98, 2.40	2.07, 2.53

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
%Change from baseline to Day 5	n	38	28	18	11	11	7
	Missing, n (%)	5 (11.6)	4 (12.5)	2 (10.0)	4 (26.7)	2 (15.4)	4 (36.4)
	Median	-60.70	-67.31	-6.26	-6.00	-64.81	-73.68
	Q25, Q75	-65.48, -56.67	-72.18, -60.95	-10.29, 8.33	-18.95, 8.75	-68.57, -60.34	-76.14, -58.73
	Min, Max	-83.7, 4.5	-82.1, -49.0	-27.6, 20.7	-40.3, 36.8	-75.3, -60.0	-76.8, -44.1
	Mean (SD)	-58.72 (15.753)	-66.21 (9.049)	-2.04 (13.156)	-4.26 (20.614)	-65.57 (5.148)	-67.35 (12.007)
	95% CI of Mean	-63.90, -53.54	-69.72, -62.70	-8.59, 4.50	-18.11, 9.60	-69.03, -62.11	-78.46, -56.24

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
Day 5, 20:00 - 21:30	n	42	32	20	14	13	10
	Missing, n (%)	1 (2.3)	0	0	1 (6.7)	0	1 (9.1)
	Geometric Mean (CV%)	2.50 (14.444)	2.20 (32.300)	5.87 (24.532)	6.38 (31.686)	2.25 (12.085)	2.66 (53.537)
	95% CI of Geometric Mean	2.39, 2.62	1.96, 2.47	5.24, 6.58	5.33, 7.63	2.08, 2.42	1.85, 3.82
	Median	2.45	2.30	5.90	6.90	2.20	2.35
	Q25, Q75	2.30, 2.70	1.95, 2.50	5.30, 6.90	5.60, 7.70	2.10, 2.30	2.10, 2.60
	Min, Max	2.0, 5.0	0.8, 5.9	3.3, 8.9	2.8, 9.7	1.9, 3.0	1.6, 8.1
	Mean (SD)	2.53 (0.453)	2.31 (0.801)	6.03 (1.360)	6.64 (1.756)	2.26 (0.291)	3.05 (2.013)
	95% CI of Mean	2.38, 2.68	2.01, 2.60	5.38, 6.67	5.62, 7.65	2.08, 2.44	1.61, 4.49

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
%Change from baseline to Day 5	n	42	32	20	14	13	10
	Missing, n (%)	1 (2.3)	0	0	1 (6.7)	0	1 (9.1)
	Median	-62.00	-70.85	-4.06	0.00	-65.63	-68.62
	Q25, Q75	-68.12, -49.06	-75.84, -64.54	-9.47, 10.80	-8.33, 7.50	-69.33, -61.11	-72.41, -45.65
	Min, Max	-78.8, -3.8	-89.7, 0.0	-19.3, 44.9	-21.1, 18.3	-75.3, -16.7	-75.8, 0.0
	Mean (SD)	-57.39 (16.364)	-67.27 (15.358)	0.15 (15.259)	-1.54 (12.828)	-62.02 (14.525)	-57.42 (24.490)
	95% CI of Mean	-62.50, -52.29	-72.81, -61.73	-7.00, 7.30	-8.96, 5.87	-70.80, -53.24	-74.95, -39.90

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=21)	>19 cig/day (N=26)	10-19 cig/day (N=19)	>19 cig/day (N=13)	10-19 cig/day (N=6)	>19 cig/day (N=3)
Baseline	n	21	26	19	13	6	3
	Geometric Mean (CV%)	5.72 (35.242)	7.19 (25.493)	6.15 (19.908)	6.37 (30.608)	5.73 (26.287)	5.91 (54.117)
	95% CI of Geometric Mean	4.89, 6.69	6.49, 7.96	5.58, 6.76	5.31, 7.63	4.37, 7.53	1.67, 20.82
	Median	5.90	7.20	6.20	6.70	6.00	6.60
	Q25, Q75	4.50, 7.00	6.10, 8.00	5.20, 7.20	5.90, 7.30	5.40, 6.80	3.40, 9.20
	Min, Max	2.2, 10.4	4.8, 12.6	3.9, 9.0	2.8, 9.5	3.6, 7.5	3.4, 9.2
	Mean (SD)	6.02 (1.885)	7.42 (1.976)	6.26 (1.215)	6.60 (1.646)	5.88 (1.361)	6.40 (2.906)
	95% CI of Mean	5.16, 6.88	6.62, 8.22	5.67, 6.85	5.60, 7.60	4.45, 7.32	-0.82, 13.62

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=21)	>19 cig/day (N=26)	10-19 cig/day (N=19)	>19 cig/day (N=13)	10-19 cig/day (N=6)	>19 cig/day (N=3)
Day 90	n	21	26	19	13	6	3
	Geometric Mean (CV%)	2.76 (36.537)	2.58 (34.447)	5.31 (24.747)	6.11 (42.927)	2.51 (42.644)	3.64 (72.671)
	95% CI of Geometric Mean	2.34, 3.24	2.25, 2.95	4.72, 5.98	4.76, 7.83	1.63, 3.85	0.72, 18.33
	Median	2.70	2.35	5.20	6.70	2.30	2.60
	Q25, Q75	2.20, 3.20	2.20, 3.10	4.50, 6.50	5.10, 8.10	2.10, 3.00	2.40, 7.70
	Min, Max	1.7, 6.3	1.6, 6.4	3.4, 8.3	2.4, 10.3	1.5, 5.0	2.4, 7.7
	Mean (SD)	2.94 (1.177)	2.74 (1.130)	5.46 (1.324)	6.54 (2.258)	2.70 (1.232)	4.23 (3.004)
	95% CI of Mean	2.40, 3.48	2.28, 3.20	4.82, 6.11	5.17, 7.91	1.40, 4.00	-3.23, 11.70

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=21)	>19 cig/day (N=26)	10-19 cig/day (N=19)	>19 cig/day (N=13)	10-19 cig/day (N=6)	>19 cig/day (N=3)
%Change from baseline to Day 90	n	21	26	19	13	6	3
	Median	-52.86	-64.44	-9.33	-4.00	-53.41	-60.61
	Q25, Q75	-63.46, -34.15	-69.74, -53.97	-22.73, 0.00	-6.94, 17.86	-72.00, -41.67	-73.91, 126.47
	Min, Max	-75.7, 45.5	-84.9, -20.0	-45.2, 22.0	-64.2, 37.3	-77.9, -10.7	-73.9, 126.5
	Mean (SD)	-47.18 (26.147)	-61.87 (13.890)	-11.73 (18.074)	0.22 (26.170)	-51.53 (24.030)	-2.68 (112.048)
	95% CI of Mean	-59.09, -35.27	-67.48, -56.25	-20.45, -3.01	-15.60, 16.03	-76.75, -26.30	-281.03, 275.66

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		40		35	
	Missing, n (%)	2 (2.5)		1 (2.4)		4 (10.3)	
	Geometric Mean (CV%)	6.69 (28.902)		6.43 (29.340)		6.59 (29.407)	
	95% CI of Geometric Mean	6.27, 7.14		5.86, 7.05		5.97, 7.29	
	Median	6.85		6.50		6.80	
	Q25, Q75	5.60, 8.10		5.75, 7.40		5.60, 8.30	
	Min, Max	2.2, 12.6		2.8, 10.9		3.4, 9.6	
	Mean (SD)	6.94 (1.854)		6.67 (1.760)		6.85 (1.779)	
	95% CI of Mean	6.52, 7.37		6.10, 7.24		6.23, 7.46	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	78	78	40	40	36	35
	Missing, n (%)	2 (2.5)	2 (2.5)	1 (2.4)	1 (2.4)	3 (7.7)	4 (10.3)
	Geometric Mean (CV%)	2.83 (30.590)		6.21 (29.655)		2.95 (40.566)	
	95% CI of Geometric Mean	2.64, 3.03		5.65, 6.82		2.58, 3.37	
	Median	2.70	-61.33	6.15	-2.56	2.60	-57.14
	Q25, Q75	2.40, 2.90	-66.67, -52.46	5.50, 7.40	-11.32, 1.00	2.40, 2.90	-65.91, -51.16
	Min, Max	1.8, 10.8	-78.6, 0.0	2.3, 9.9	-22.5, 33.8	1.8, 8.9	-75.0, 0.0
	Mean (SD)	2.99 (1.362)	-54.53 (19.900)	6.45 (1.664)	-2.64 (12.606)	3.23 (1.790)	-51.01 (23.539)
	95% CI of Mean	2.68, 3.31	-59.02, -50.04	5.91, 6.98	-6.67, 1.40	2.62, 3.84	-59.10, -42.91

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	78	78	40	40	36	35
	Missing, n (%)	2 (2.5)	2 (2.5)	1 (2.4)	1 (2.4)	3 (7.7)	4 (10.3)
	Geometric Mean (CV%)	2.60 (28.694)		6.32 (31.370)		2.79 (45.205)	
	95% CI of Geometric Mean	2.44, 2.78		5.73, 6.98		2.41, 3.23	
	Median	2.50	-64.20	6.10	-4.17	2.45	-62.30
	Q25, Q75	2.30, 2.70	-69.70, -54.72	5.60, 8.00	-11.92, 0.00	2.20, 2.80	-70.53, -50.00
	Min, Max	1.6, 10.8	-84.1, 0.0	2.3, 10.6	-25.0, 62.7	1.5, 8.9	-77.1, 0.0
	Mean (SD)	2.74 (1.226)	-58.03 (18.771)	6.59 (1.788)	-0.03 (19.786)	3.12 (1.869)	-52.88 (24.685)
	95% CI of Mean	2.46, 3.02	-62.27, -53.79	6.01, 7.16	-6.37, 6.30	2.48, 3.76	-61.37, -44.40

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	78	78	40	40	36	35
	Missing, n (%)	2 (2.5)	2 (2.5)	1 (2.4)	1 (2.4)	3 (7.7)	4 (10.3)
	Geometric Mean (CV%)	2.44 (22.773)		6.46 (28.093)		2.48 (46.187)	
	95% CI of Geometric Mean	2.32, 2.57		5.91, 7.06		2.13, 2.89	
	Median	2.40	-64.17	6.70	0.00	2.35	-66.04
	Q25, Q75	2.20, 2.70	-71.21, -59.09	5.65, 7.50	-9.88, 13.75	1.90, 2.60	-72.41, -58.73
	Min, Max	1.4, 5.9	-78.2, 9.1	2.8, 10.8	-32.2, 37.3	1.3, 8.9	-77.3, 0.0
	Mean (SD)	2.51 (0.672)	-61.25 (15.573)	6.68 (1.706)	1.95 (17.778)	2.80 (1.841)	-58.41 (22.602)
	95% CI of Mean	2.35, 2.67	-64.77, -57.74	6.13, 7.23	-3.74, 7.64	2.17, 3.43	-66.18, -50.64

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	78	78	40	40	36	35
	Missing, n (%)	2 (2.5)	2 (2.5)	1 (2.4)	1 (2.4)	3 (7.7)	4 (10.3)
	Geometric Mean (CV%)	2.44 (17.591)		6.45 (29.461)		2.41 (45.012)	
	95% CI of Geometric Mean	2.34, 2.55		5.87, 7.08		2.08, 2.79	
	Median	2.40	-63.75	6.50	0.00	2.20	-67.37
	Q25, Q75	2.30, 2.60	-71.08, -55.93	5.95, 7.85	-8.14, 9.31	2.00, 2.50	-72.41, -60.00
	Min, Max	1.5, 5.9	-81.0, 4.5	2.6, 9.2	-23.2, 33.9	1.2, 8.9	-81.8, 0.0
	Mean (SD)	2.48 (0.511)	-61.28 (14.923)	6.68 (1.636)	1.21 (13.828)	2.72 (1.823)	-59.56 (22.264)
	95% CI of Mean	2.36, 2.60	-64.65, -57.91	6.15, 7.21	-3.22, 5.63	2.09, 3.34	-67.21, -51.90

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, Within 15 Min Prior To Smoking	n	71	71	37	37		
	Missing, n (%)	9 (11.3)	9 (11.3)	4 (9.8)	4 (9.8)		
	Geometric Mean (CV%)	2.39 (16.579)		4.26 (21.788)			
	95% CI of Geometric Mean	2.30, 2.49		3.96, 4.58			
	Median	2.40	-64.41	4.30	-35.94		
	Q25, Q75	2.20, 2.60	-70.13, -55.36	3.80, 4.90	-42.62, -26.67		
	Min, Max	1.5, 4.9	-82.6, -9.1	2.5, 6.7	-57.3, -5.9		
	Mean (SD)	2.43 (0.438)	-61.99 (12.930)	4.35 (0.923)	-33.89 (13.076)		
	95% CI of Mean	2.32, 2.53	-65.06, -58.93	4.04, 4.67	-38.25, -29.52		

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 08:00 - 09:30	n					30	30
	Missing, n (%)					9 (23.1)	9 (23.1)
	Geometric Mean (CV%)					2.23 (18.886)	
	95% CI of Geometric Mean					2.08, 2.40	
	Median					2.20	-66.82
	Q25, Q75					1.90, 2.60	-73.33, -58.73
	Min, Max					1.5, 3.1	-78.8, -16.7
	Mean (SD)					2.27 (0.426)	-64.01 (13.637)
	95% CI of Mean					2.11, 2.43	-69.10, -58.91

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 12:00 - 13:30	n	69	69	36	36	29	29
	Missing, n (%)	11 (13.8)	11 (13.8)	5 (12.2)	5 (12.2)	10 (25.6)	10 (25.6)
	Geometric Mean (CV%)	2.50 (14.130)		6.04 (28.874)		2.32 (16.059)	
	95% CI of Geometric Mean	2.41, 2.59		5.48, 6.65		2.18, 2.47	
	Median	2.50	-63.24	6.20	-9.48	2.40	-68.00
	Q25, Q75	2.30, 2.70	-69.05, -55.00	5.30, 7.45	-15.32, 2.49	2.20, 2.60	-71.74, -55.88
	Min, Max	1.7, 3.8	-81.7, 9.1	2.6, 9.3	-39.7, 36.8	1.6, 3.1	-79.2, -26.5
	Mean (SD)	2.52 (0.357)	-60.58 (13.759)	6.26 (1.568)	-6.81 (15.245)	2.34 (0.361)	-62.11 (13.447)
	95% CI of Mean	2.43, 2.61	-63.89, -57.27	5.72, 6.79	-11.97, -1.65	2.20, 2.49	-67.23, -56.99

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 16:00 - 17:30	n	70	70	35	35	28	28
	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	11 (28.2)	11 (28.2)
	Geometric Mean (CV%)	2.39 (18.414)		6.35 (25.248)		2.22 (12.928)	
	95% CI of Geometric Mean	2.29, 2.51		5.83, 6.92		2.10, 2.34	
	Median	2.40	-64.14	6.20	-6.06	2.20	-68.00
	Q25, Q75	2.20, 2.60	-69.70, -57.58	5.40, 7.80	-13.68, 8.33	2.00, 2.40	-73.38, -60.32
	Min, Max	1.4, 5.2	-83.7, 4.5	3.5, 9.3	-40.3, 36.8	1.7, 2.9	-77.1, -26.5
	Mean (SD)	2.44 (0.484)	-62.14 (13.472)	6.54 (1.554)	-3.64 (15.600)	2.24 (0.289)	-64.99 (11.226)
	95% CI of Mean	2.32, 2.56	-65.35, -58.92	6.00, 7.08	-9.00, 1.73	2.12, 2.35	-69.35, -60.63

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 20:00 - 21:30	n	78	78	40	40	36	35
	Missing, n (%)	2 (2.5)	2 (2.5)	1 (2.4)	1 (2.4)	3 (7.7)	4 (10.3)
	Geometric Mean (CV%)	2.37 (23.858)		6.26 (26.656)		2.50 (44.556)	
	95% CI of Geometric Mean	2.24, 2.51		5.75, 6.81		2.16, 2.89	
	Median	2.40	-65.17	6.50	-2.87	2.20	-66.67
	Q25, Q75	2.20, 2.60	-72.53, -56.00	5.70, 7.40	-11.36, 9.72	2.05, 2.60	-72.41, -58.00
	Min, Max	0.8, 5.9	-89.7, 0.0	2.8, 9.7	-33.9, 44.9	1.6, 8.9	-78.2, 0.0
	Mean (SD)	2.44 (0.618)	-61.82 (16.229)	6.46 (1.508)	-1.43 (15.612)	2.81 (1.841)	-57.93 (22.863)
	95% CI of Mean	2.29, 2.58	-65.48, -58.15	5.97, 6.94	-6.43, 3.57	2.18, 3.44	-65.79, -50.07

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	78	78	40	40	36	35
	Missing, n (%)	2 (2.5)	2 (2.5)	1 (2.4)	1 (2.4)	3 (7.7)	4 (10.3)
	Geometric Mean (CV%)	3.19 (39.911)		6.23 (33.331)		3.33 (52.944)	
	95% CI of Geometric Mean	2.92, 3.48		5.61, 6.91		2.81, 3.95	
	Median	3.00	-50.85	6.25	0.00	2.95	-54.74
	Q25, Q75	2.50, 4.30	-65.52, -29.55	5.00, 8.00	-17.39, 9.93	2.30, 4.35	-64.71, -29.41
	Min, Max	1.5, 7.7	-83.3, 22.7	2.4, 10.6	-49.5, 71.0	1.7, 8.9	-79.5, 64.7
	Mean (SD)	3.43 (1.378)	-46.95 (24.208)	6.53 (1.959)	-0.67 (22.735)	3.78 (2.089)	-42.77 (30.694)
	95% CI of Mean	3.12, 3.75	-52.41, -41.48	5.90, 7.16	-7.95, 6.60	3.07, 4.49	-53.32, -32.23

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	78	78	40	40	36	35
	Missing, n (%)	2 (2.5)	2 (2.5)	1 (2.4)	1 (2.4)	3 (7.7)	4 (10.3)
	Geometric Mean (CV%)	3.16 (42.084)		5.67 (38.273)		3.65 (55.721)	
	95% CI of Geometric Mean	2.88, 3.47		5.03, 6.38		3.05, 4.35	
	Median	2.90	-52.86	6.25	-7.08	3.65	-38.46
	Q25, Q75	2.30, 4.20	-67.57, -31.76	4.50, 7.25	-23.84, 5.32	2.40, 5.50	-66.13, -26.98
	Min, Max	1.3, 9.2	-84.1, 36.4	2.4, 12.7	-64.2, 54.9	1.5, 8.9	-78.3, 126.5
	Mean (SD)	3.44 (1.535)	-47.62 (24.220)	6.03 (2.070)	-8.26 (25.087)	4.16 (2.169)	-36.22 (37.267)
	95% CI of Mean	3.09, 3.79	-53.08, -42.15	5.36, 6.69	-16.29, -0.23	3.42, 4.89	-49.03, -23.41

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.2 Descriptive Statistics of Blood COHb (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	78	78	40	40	36	35
	Missing, n (%)	2 (2.5)	2 (2.5)	1 (2.4)	1 (2.4)	3 (7.7)	4 (10.3)
	Geometric Mean (CV%)	3.00 (40.125)		5.76 (35.496)		3.63 (48.034)	
	95% CI of Geometric Mean	2.75, 3.28		5.16, 6.44		3.10, 4.24	
	Median	2.70	-55.83	6.20	-7.15	3.75	-44.29
	Q25, Q75	2.30, 3.80	-66.18, -39.42	4.95, 7.40	-20.43, 10.76	2.55, 4.35	-62.20, -20.59
	Min, Max	1.6, 7.5	-84.9, 45.5	2.4, 10.3	-64.2, 37.3	1.5, 8.9	-77.9, 126.5
	Mean (SD)	3.25 (1.403)	-50.95 (22.531)	6.08 (1.897)	-7.22 (22.865)	4.03 (1.976)	-37.06 (36.748)
	95% CI of Mean	2.92, 3.57	-56.03, -45.86	5.47, 6.69	-14.54, 0.10	3.35, 4.70	-49.69, -24.43

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.3 Descriptive Statistics of Blood COHb (%) - Compliant Population****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		34		23	
	Missing, n (%)	1 (1.3)		1 (2.9)		1 (4.2)	
	Geometric Mean (CV%)	6.66 (29.163)		6.16 (28.377)		6.54 (28.455)	
	95% CI of Geometric Mean	6.23, 7.13		5.59, 6.80		5.79, 7.38	
	Median	6.85		6.25		6.80	
	Q25, Q75	5.60, 8.10		5.60, 7.30		5.40, 8.10	
	Min, Max	2.2, 12.6		2.8, 9.7		3.4, 9.5	
	Mean (SD)	6.92 (1.859)		6.38 (1.586)		6.77 (1.730)	
	95% CI of Mean	6.49, 7.36		5.82, 6.94		6.02, 7.52	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.3 Descriptive Statistics of Blood COHb (%) - Compliant Population****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Geometric Mean (CV%)	2.84 (31.339)		5.97 (28.944)		2.95 (34.371)	
	95% CI of Geometric Mean	2.64, 3.05		5.40, 6.60		2.55, 3.42	
	Median	2.70	-61.38	5.90	-2.56	2.70	-56.00
	Q25, Q75	2.40, 2.90	-66.67, -51.79	5.40, 7.20	-11.25, 0.00	2.50, 3.10	-65.85, -51.72
	Min, Max	1.8, 10.8	-78.6, 0.0	2.3, 9.1	-20.7, 33.8	1.8, 8.1	-72.8, 0.0
	Mean (SD)	3.01 (1.395)	-54.09 (20.291)	6.18 (1.521)	-2.50 (11.599)	3.15 (1.402)	-51.09 (22.557)
	95% CI of Mean	2.69, 3.34	-58.79, -49.38	5.65, 6.72	-6.55, 1.56	2.54, 3.76	-60.85, -41.33

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.3 Descriptive Statistics of Blood COHb (%) - Compliant Population****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Geometric Mean (CV%)	2.62 (29.207)		6.07 (31.089)		2.79 (40.447)	
	95% CI of Geometric Mean	2.44, 2.80		5.45, 6.75		2.36, 3.31	
	Median	2.50	-63.43	5.95	-4.14	2.60	-57.41
	Q25, Q75	2.30, 2.70	-69.70, -54.00	5.60, 7.30	-11.34, 0.00	2.30, 2.80	-70.53, -50.94
	Min, Max	1.6, 10.8	-84.1, 0.0	2.3, 10.6	-25.0, 62.7	1.5, 8.1	-74.7, 0.0
	Mean (SD)	2.76 (1.254)	-57.54 (19.109)	6.32 (1.685)	0.19 (20.508)	3.04 (1.511)	-53.09 (23.402)
	95% CI of Mean	2.47, 3.06	-61.97, -53.11	5.73, 6.91	-6.97, 7.35	2.38, 3.70	-63.22, -42.97

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.3 Descriptive Statistics of Blood COHb (%) - Compliant Population****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Geometric Mean (CV%)	2.46 (23.229)		6.21 (27.183)		2.39 (38.557)	
	95% CI of Geometric Mean	2.32, 2.59		5.66, 6.83		2.03, 2.81	
	Median	2.40	-63.98	6.50	0.00	2.40	-66.04
	Q25, Q75	2.20, 2.70	-71.21, -58.00	5.40, 7.20	-6.85, 15.00	1.90, 2.60	-71.79, -60.29
	Min, Max	1.4, 5.9	-78.2, 9.1	2.8, 10.8	-32.2, 37.3	1.3, 8.1	-75.3, 0.0
	Mean (SD)	2.53 (0.685)	-60.86 (15.839)	6.41 (1.554)	2.39 (18.251)	2.59 (1.369)	-60.75 (18.952)
	95% CI of Mean	2.36, 2.69	-64.53, -57.18	5.87, 6.96	-3.98, 8.77	1.99, 3.18	-68.95, -52.55

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.3 Descriptive Statistics of Blood COHb (%) - Compliant Population****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Geometric Mean (CV%)	2.44 (18.040)		6.17 (29.632)		2.29 (34.377)	
	95% CI of Geometric Mean	2.34, 2.55		5.57, 6.83		1.98, 2.65	
	Median	2.40	-63.75	6.35	0.00	2.20	-67.95
	Q25, Q75	2.30, 2.60	-71.08, -55.56	5.90, 7.30	-6.67, 8.62	1.90, 2.50	-72.41, -60.94
	Min, Max	1.5, 5.9	-81.0, 4.5	2.6, 9.2	-23.2, 33.9	1.5, 8.1	-76.8, 0.0
	Mean (SD)	2.48 (0.524)	-61.09 (15.228)	6.40 (1.596)	0.84 (12.736)	2.46 (1.298)	-62.37 (18.050)
	95% CI of Mean	2.36, 2.61	-64.62, -57.55	5.84, 6.96	-3.61, 5.29	1.89, 3.03	-70.18, -54.56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.3 Descriptive Statistics of Blood COHb (%) - Compliant Population****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, Within 15 Min Prior To Smoking	n	67	67	31	31		
	Missing, n (%)	8 (10.7)	8 (10.7)	4 (11.4)	4 (11.4)		
	Geometric Mean (CV%)	2.38 (16.932)		4.22 (23.001)			
	95% CI of Geometric Mean	2.28, 2.49		3.88, 4.59			
	Median	2.40	-64.41	4.30	-33.33		
	Q25, Q75	2.20, 2.60	-70.13, -55.36	3.60, 4.90	-42.47, -23.08		
	Min, Max	1.5, 4.9	-82.6, -9.1	2.5, 6.7	-52.2, -5.9		
	Mean (SD)	2.42 (0.448)	-61.94 (13.114)	4.33 (0.972)	-31.92 (12.304)		
	95% CI of Mean	2.30, 2.53	-65.14, -58.73	3.96, 4.69	-36.43, -27.40		

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.3 Descriptive Statistics of Blood COHb (%) - Compliant Population****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 08:00 - 09:30	n					21	21
	Missing, n (%)					3 (12.5)	3 (12.5)
	Geometric Mean (CV%)					2.22 (20.780)	
	95% CI of Geometric Mean					2.01, 2.44	
	Median					2.10	-67.37
	Q25, Q75					1.90, 2.60	-73.33, -58.73
	Min, Max					1.5, 3.1	-77.9, -16.7
	Mean (SD)					2.26 (0.469)	-64.09 (13.636)
	95% CI of Mean					2.04, 2.48	-70.30, -57.88

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.3 Descriptive Statistics of Blood COHb (%) - Compliant Population****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 12:00 - 13:30	n	65	65	30	30	19	19
	Missing, n (%)	10 (13.3)	10 (13.3)	5 (14.3)	5 (14.3)	5 (20.8)	5 (20.8)
	Geometric Mean (CV%)	2.49 (14.337)		5.86 (30.041)		2.32 (15.470)	
	95% CI of Geometric Mean	2.40, 2.58		5.25, 6.55		2.15, 2.50	
	Median	2.50	-63.24	6.00	-6.01	2.40	-65.85
	Q25, Q75	2.30, 2.70	-69.05, -55.00	5.20, 7.00	-13.73, 5.00	2.10, 2.60	-71.43, -55.88
	Min, Max	1.7, 3.8	-81.7, 9.1	2.6, 9.3	-39.7, 36.8	1.6, 3.0	-79.2, -27.8
	Mean (SD)	2.51 (0.362)	-60.48 (14.013)	6.09 (1.607)	-5.45 (15.869)	2.34 (0.344)	-62.57 (12.598)
	95% CI of Mean	2.42, 2.61	-63.95, -57.00	5.49, 6.70	-11.38, 0.48	2.17, 2.51	-68.65, -56.49

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.3 Descriptive Statistics of Blood COHb (%) - Compliant Population****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 16:00 - 17:30	n	66	66	29	29	18	18
	Missing, n (%)	9 (12.0)	9 (12.0)	6 (17.1)	6 (17.1)	6 (25.0)	6 (25.0)
	Geometric Mean (CV%)	2.39 (18.884)		6.14 (25.378)		2.22 (12.984)	
	95% CI of Geometric Mean	2.28, 2.51		5.58, 6.76		2.07, 2.37	
	Median	2.40	-63.96	6.10	-6.06	2.25	-68.00
	Q25, Q75	2.20, 2.60	-69.70, -57.38	5.30, 7.60	-13.40, 8.33	2.00, 2.40	-73.68, -60.34
	Min, Max	1.4, 5.2	-83.7, 4.5	3.5, 9.3	-40.3, 36.8	1.7, 2.7	-76.8, -44.1
	Mean (SD)	2.44 (0.497)	-61.90 (13.755)	6.32 (1.538)	-2.88 (16.064)	2.23 (0.283)	-66.26 (8.202)
	95% CI of Mean	2.31, 2.56	-65.28, -58.51	5.73, 6.91	-9.00, 3.23	2.09, 2.38	-70.34, -62.18

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.3 Descriptive Statistics of Blood COHb (%) - Compliant Population****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 20:00 - 21:30	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Geometric Mean (CV%)	2.37 (24.420)		6.07 (27.534)		2.42 (35.466)	
	95% CI of Geometric Mean	2.23, 2.51		5.52, 6.68		2.08, 2.81	
	Median	2.40	-65.17	6.25	-1.28	2.20	-66.67
	Q25, Q75	2.20, 2.60	-72.53, -52.73	5.60, 7.30	-8.33, 9.09	2.10, 2.50	-70.45, -60.38
	Min, Max	0.8, 5.9	-89.7, 0.0	2.8, 9.7	-21.1, 44.9	1.6, 8.1	-75.8, 0.0
	Mean (SD)	2.43 (0.633)	-61.67 (16.578)	6.28 (1.540)	-0.55 (14.128)	2.60 (1.365)	-60.02 (19.127)
	95% CI of Mean	2.28, 2.59	-65.51, -57.82	5.73, 6.82	-5.48, 4.39	2.01, 3.20	-68.30, -51.75

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.3 Descriptive Statistics of Blood COHb (%) - Compliant Population****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=32)		mCC (N=34)		SA (N=8)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	32		34		8	
	Geometric Mean (CV%)	6.41 (37.360)		6.21 (28.196)		6.92 (22.303)	
	95% CI of Geometric Mean	5.62, 7.31		5.64, 6.85		5.75, 8.33	
	Median	6.45		6.35		6.70	
	Q25, Q75	5.25, 8.05		5.70, 7.30		5.90, 8.35	
	Min, Max	2.2, 12.6		2.8, 9.7		5.2, 9.5	
	Mean (SD)	6.81 (2.363)		6.43 (1.571)		7.08 (1.589)	
	95% CI of Mean	5.95, 7.66		5.87, 6.98		5.74, 8.41	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.3 Descriptive Statistics of Blood COHb (%) - Compliant Population****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=32)		mCC (N=34)		SA (N=8)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	32	32	34	34	8	8
	Geometric Mean (CV%)	2.88 (40.567)		6.13 (34.149)		2.58 (28.511)	
	95% CI of Geometric Mean	2.50, 3.33		5.46, 6.89		2.04, 3.27	
	Median	2.70	-51.87	6.15	0.00	2.35	-61.06
	Q25, Q75	2.35, 3.60	-69.69, -29.13	5.00, 8.00	-17.24, 10.45	2.30, 3.05	-71.79, -55.49
	Min, Max	1.5, 7.3	-83.3, 22.7	2.4, 10.6	-31.8, 71.0	1.7, 4.3	-75.0, -36.5
	Mean (SD)	3.12 (1.341)	-47.91 (28.170)	6.45 (1.969)	0.97 (22.635)	2.68 (0.802)	-61.03 (12.692)
	95% CI of Mean	2.63, 3.60	-58.07, -37.75	5.76, 7.14	-6.93, 8.87	2.00, 3.35	-71.64, -50.41

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.3 Descriptive Statistics of Blood COHb (%) - Compliant Population****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=36)		mCC (N=34)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	36		34		7	
	Geometric Mean (CV%)	6.47 (34.931)		6.19 (28.377)		6.28 (30.056)	
	95% CI of Geometric Mean	5.77, 7.27		5.62, 6.83		4.78, 8.25	
	Median	6.50		6.35		6.60	
	Q25, Q75	5.50, 7.90		5.60, 7.30		5.40, 7.50	
	Min, Max	2.2, 12.6		2.8, 9.7		3.6, 9.2	
	Mean (SD)	6.83 (2.214)		6.41 (1.583)		6.50 (1.734)	
	95% CI of Mean	6.07, 7.58		5.85, 6.97		4.89, 8.11	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.3 Descriptive Statistics of Blood COHb (%) - Compliant Population****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=36)		mCC (N=34)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	36	36	34	34	7	7
	Geometric Mean (CV%)	2.91 (41.074)		5.55 (39.316)		2.11 (28.134)	
	95% CI of Geometric Mean	2.54, 3.33		4.86, 6.34		1.63, 2.73	
	Median	2.75	-56.17	6.25	-4.14	2.00	-74.24
	Q25, Q75	2.20, 3.35	-69.06, -34.12	4.50, 7.20	-19.64, 12.90	1.70, 2.80	-77.94, -48.15
	Min, Max	1.8, 9.2	-84.1, 36.4	2.4, 12.7	-64.2, 54.9	1.5, 3.3	-78.3, -41.7
	Mean (SD)	3.18 (1.610)	-49.04 (27.708)	5.93 (2.089)	-6.47 (25.895)	2.19 (0.639)	-63.34 (16.359)
	95% CI of Mean	2.63, 3.73	-58.42, -39.66	5.19, 6.66	-15.51, 2.57	1.59, 2.78	-78.47, -48.20

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.3 Descriptive Statistics of Blood COHb (%) - Compliant Population****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=41)		mCC (N=31)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	41		31		7	
	Geometric Mean (CV%)	6.49 (33.143)		6.25 (24.693)		6.28 (30.056)	
	95% CI of Geometric Mean	5.86, 7.20		5.71, 6.84		4.78, 8.25	
	Median	6.60		6.40		6.60	
	Q25, Q75	5.50, 7.80		5.60, 7.30		5.40, 7.50	
	Min, Max	2.2, 12.6		2.8, 9.5		3.6, 9.2	
	Mean (SD)	6.81 (2.111)		6.42 (1.408)		6.50 (1.734)	
	95% CI of Mean	6.14, 7.49		5.90, 6.94		4.89, 8.11	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.1.3 Descriptive Statistics of Blood COHb (%) - Compliant Population****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=41)		mCC (N=31)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	41	41	31	31	7	7
	Geometric Mean (CV%)	2.62 (34.892)		5.69 (33.054)		2.27 (22.346)	
	95% CI of Geometric Mean	2.35, 2.92		5.05, 6.41		1.84, 2.79	
	Median	2.40	-57.97	6.00	-6.94	2.40	-60.61
	Q25, Q75	2.20, 3.10	-68.00, -50.79	4.90, 7.00	-18.75, 11.67	2.10, 2.60	-73.91, -53.13
	Min, Max	1.6, 6.4	-84.9, 45.5	2.4, 10.3	-64.2, 37.3	1.5, 3.0	-77.9, -41.7
	Mean (SD)	2.79 (1.128)	-55.96 (21.500)	5.96 (1.803)	-6.08 (22.038)	2.31 (0.475)	-61.85 (13.285)
	95% CI of Mean	2.43, 3.15	-62.75, -49.17	5.30, 6.63	-14.17, 2.01	1.87, 2.76	-74.14, -49.56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		30		21	
	Missing, n (%)	10 (13.3)		5 (14.3)		3 (12.5)	
	BLOQ, n (%)	1 (1.5)		4 (13.3)		1 (4.8)	
	Geometric Mean (CV%)	1416.94 (109.332)		922.66 (170.171)		1145.57 (134.630)	
	95% CI of Geometric Mean	1137.42, 1765.14		596.93, 1426.12		721.09, 1819.91	
	Median	1434.51		1459.42		1634.33	
	Q25, Q75	991.54, 2764.71		396.83, 2127.66		579.88, 2450.70	
	Min, Max	155.7, 10792.9		96.3, 5519.7		125.0, 5922.7	
	Mean (SD)	2001.13 (1760.863)		1517.33 (1304.149)		1683.88 (1347.452)	
	95% CI of Mean	1564.81, 2437.46		1030.35, 2004.31		1070.52, 2297.23	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	4 (5.6)		2 (6.1)		3 (13.6)	
	Geometric Mean (CV%)	385.21 (78.638)		877.17 (176.153)		339.98 (95.178)	
	95% CI of Geometric Mean	326.87, 453.97		575.59, 1336.76		238.13, 485.40	
	Median	369.49	-75.37	1525.50	-10.94	418.21	-74.52
	Q25, Q75	255.12, 634.03	-80.42, -63.48	365.14, 2261.90	-29.84, 16.61	201.48, 564.24	-76.59, -63.21
	Min, Max	104.6, 4505.1	-89.9, 8.3	75.0, 3297.0	-51.2, 178.8	57.1, 1368.4	-88.4, 29.4
	Mean (SD)	506.04 (554.844)	-67.76 (22.079)	1430.16 (1064.878)	6.82 (59.654)	446.36 (328.007)	-66.45 (24.602)
	95% CI of Mean	374.70, 637.37	-73.24, -62.29	1052.57, 1807.76	-15.46, 29.10	300.92, 591.79	-77.65, -55.24

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	30 (42.3)		7 (21.2)		10 (45.5)	
	Geometric Mean (CV%)	120.03 (70.380)		629.39 (292.537)		111.83 (70.471)	
	95% CI of Geometric Mean	103.29, 139.48		369.44, 1072.24		84.38, 148.19	
	Median	136.25	-92.16	1120.85	-20.08	99.59	-93.10
	Q25, Q75	79.74, 172.75	-94.02, -88.93	230.91, 1824.00	-39.43, 4.32	62.66, 247.37	-94.53, -82.80
	Min, Max	29.1, 460.5	-98.8, 58.0	23.6, 4601.5	-88.9, 302.0	46.3, 310.9	-97.6, -16.2
	Mean (SD)	144.19 (86.811)	-86.27 (20.852)	1250.70 (1109.114)	-9.08 (71.967)	135.92 (88.194)	-84.09 (19.397)
	95% CI of Mean	123.64, 164.74	-91.44, -81.10	857.42, 1643.98	-35.96, 17.80	96.81, 175.02	-92.92, -75.25

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	33 (46.5)		5 (15.2)		12 (54.5)	
	Geometric Mean (CV%)	107.39 (57.153)		855.56 (268.299)		90.01 (58.160)	
	95% CI of Geometric Mean	94.69, 121.80		511.54, 1430.93		70.85, 114.36	
	Median	104.17	-92.66	1651.82	-12.04	87.50	-94.87
	Q25, Q75	73.17, 152.46	-95.13, -89.19	244.44, 2437.57	-28.82, 18.68	51.12, 137.72	-96.47, -86.30
	Min, Max	33.3, 396.2	-98.8, -19.9	56.1, 5332.6	-86.9, 270.1	45.5, 253.2	-98.2, 19.8
	Mean (SD)	123.67 (70.479)	-89.67 (11.142)	1686.24 (1464.089)	8.07 (67.346)	103.67 (58.503)	-81.87 (30.268)
	95% CI of Mean	106.99, 140.36	-92.43, -86.90	1167.09, 2205.38	-17.08, 33.22	77.73, 129.62	-95.66, -68.09

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	30 (42.3)		3 (9.1)		8 (36.4)	
	Geometric Mean (CV%)	130.57 (88.338)		745.66 (260.880)		137.12 (73.671)	
	95% CI of Geometric Mean	109.08, 156.28		448.53, 1239.63		102.40, 183.61	
	Median	136.60	-91.40	1385.07	-9.93	136.41	-91.45
	Q25, Q75	74.63, 223.44	-94.36, -82.44	179.86, 2602.92	-41.88, 25.25	91.49, 192.31	-94.38, -83.78
	Min, Max	23.0, 1168.4	-99.2, 57.0	49.5, 4308.3	-79.0, 256.8	42.4, 465.7	-96.9, 53.8
	Mean (SD)	173.38 (157.127)	-83.65 (23.588)	1469.85 (1281.378)	2.07 (68.094)	168.33 (115.562)	-73.16 (43.762)
	95% CI of Mean	136.19, 210.58	-89.50, -77.80	1015.49, 1924.22	-23.36, 27.51	117.09, 219.57	-93.09, -53.24

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	48 (67.6)		6 (18.2)		13 (59.1)	
	Geometric Mean (CV%)	113.01 (60.404)		760.36 (261.147)		93.99 (52.409)	
	95% CI of Geometric Mean	99.03, 128.96		457.27, 1264.34		75.54, 116.94	
	Median	116.55	-92.50	1401.87	-16.84	94.32	-94.93
	Q25, Q75	79.19, 168.78	-94.51, -87.31	182.28, 2495.18	-43.16, 17.27	58.41, 144.08	-95.65, -84.76
	Min, Max	23.6, 686.5	-98.8, -10.1	43.5, 4975.4	-67.6, 334.7	45.0, 200.0	-98.2, 46.0
	Mean (SD)	132.53 (90.045)	-87.52 (14.545)	1518.14 (1383.793)	2.27 (77.542)	105.29 (50.905)	-82.14 (32.744)
	95% CI of Mean	111.21, 153.84	-91.13, -83.91	1027.46, 2008.82	-26.69, 31.23	82.72, 127.87	-97.05, -67.23

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	36		29		12	
	Missing, n (%)	4 (10.0)		5 (14.7)		1 (7.7)	
	Geometric Mean (CV%)	1434.11 (127.630)		981.48 (164.419)		1019.37 (177.252)	
	95% CI of Geometric Mean	1028.28, 2000.10		635.12, 1516.71		477.94, 2174.11	
	Median	1292.78		1527.03		1414.76	
	Q25, Q75	867.32, 2952.82		437.28, 2127.66		445.91, 2455.64	
	Min, Max	155.7, 10792.9		96.3, 5519.7		125.0, 5922.7	
	Mean (SD)	2188.12 (2135.839)		1568.55 (1299.569)		1695.64 (1617.719)	
	95% CI of Mean	1465.45, 2910.79		1074.21, 2062.88		667.78, 2723.49	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	39	36	32	29	13	12
	Missing, n (%)	1 (2.5)	4 (10.0)	2 (5.9)	5 (14.7)	0	1 (7.7)
	BLOQ, n (%)	7 (17.9)		3 (9.4)		2 (15.4)	
	Geometric Mean (CV%)	297.29 (114.408)		1017.53 (239.489)		310.59 (113.194)	
	95% CI of Geometric Mean	220.99, 399.91		618.43, 1674.17		179.41, 537.69	
	Median	292.35	-76.16	2073.52	19.39	322.28	-83.56
	Q25, Q75	166.45, 713.35	-88.99, -60.49	276.92, 2642.23	-8.07, 70.74	200.99, 674.17	-89.03, 19.03
	Min, Max	53.9, 2041.6	-98.5, 22.9	31.4, 4646.6	-82.3, 172.7	53.2, 1012.9	-95.5, 116.1
	Mean (SD)	436.97 (404.458)	-66.02 (33.577)	1797.17 (1299.702)	26.74 (62.723)	433.07 (337.430)	-39.18 (73.569)
	95% CI of Mean	305.85, 568.08	-77.38, -54.65	1328.57, 2265.76	2.88, 50.61	229.16, 636.98	-85.93, 7.57

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	35		30		11	
	Missing, n (%)	4 (10.3)		5 (14.3)		1 (8.3)	
	Geometric Mean (CV%)	1400.11 (126.639)		977.50 (159.425)		742.11 (158.600)	
	95% CI of Geometric Mean	1000.51, 1959.31		642.32, 1487.59		349.40, 1576.17	
	Median	1244.93		1459.42		1025.41	
	Q25, Q75	688.37, 3070.45		437.28, 2127.66		308.19, 2450.70	
	Min, Max	155.7, 10792.9		96.3, 5519.7		125.0, 2736.4	
	Mean (SD)	2151.53 (2164.217)		1545.23 (1283.339)		1180.99 (996.396)	
	95% CI of Mean	1408.09, 2894.97		1066.01, 2024.44		511.60, 1850.38	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	35	33	30	11	11
	Missing, n (%)	0	4 (10.3)	2 (5.7)	5 (14.3)	1 (8.3)	1 (8.3)
	BLOQ, n (%)	8 (20.5)		4 (12.1)		3 (27.3)	
	Geometric Mean (CV%)	245.94 (93.944)		882.02 (229.819)		244.33 (152.040)	
	95% CI of Geometric Mean	190.04, 318.28		545.41, 1426.38		117.13, 509.62	
	Median	249.39	-84.59	1294.12	-12.26	260.71	-54.51
	Q25, Q75	130.27, 483.94	-93.50, -69.72	411.72, 2313.43	-41.92, 64.88	108.46, 342.64	-93.96, 1.36
	Min, Max	41.3, 1133.8	-98.0, 28.9	28.2, 5838.9	-59.6, 208.8	52.4, 1676.8	-96.0, 189.2
	Mean (SD)	328.98 (257.411)	-72.74 (31.526)	1585.34 (1379.609)	12.13 (69.468)	438.82 (553.840)	-29.15 (86.362)
	95% CI of Mean	245.54, 412.43	-83.57, -61.91	1096.15, 2074.53	-13.81, 38.08	66.74, 810.90	-87.17, 28.87

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	43		29		9	
	Missing, n (%)	4 (8.5)		3 (9.4)		0	
	Geometric Mean (CV%)	1429.33 (119.449)		948.90 (161.404)		595.28 (158.967)	
	95% CI of Geometric Mean	1069.75, 1909.77		616.80, 1459.81		251.15, 1410.96	
	Median	1340.63		1391.81		579.88	
	Q25, Q75	743.10, 2835.20		437.28, 2042.01		308.19, 1195.19	
	Min, Max	155.7, 10792.9		96.3, 5519.7		125.0, 2736.4	
	Mean (SD)	2115.39 (2001.030)		1518.77 (1297.703)		989.54 (986.185)	
	95% CI of Mean	1499.56, 2731.22		1025.15, 2012.40		231.48, 1747.59	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	43	32	29	9	9
	Missing, n (%)	0	4 (8.5)	0	3 (9.4)	0	
	BLOQ, n (%)	9 (19.1)		0		2 (22.2)	
	Geometric Mean (CV%)	260.98 (97.527)		1040.71 (176.488)		243.00 (100.030)	
	95% CI of Geometric Mean	205.28, 331.79		677.79, 1597.94		128.12, 460.90	
	Median	261.18	-84.74	1709.96	-1.63	266.20	-79.84
	Q25, Q75	130.28, 475.97	-90.16, -65.10	387.33, 2684.83	-28.72, 46.10	171.46, 373.64	-85.65, 19.78
	Min, Max	62.3, 1359.2	-97.8, 68.3	55.4, 6715.6	-50.9, 324.0	60.2, 1141.2	-89.2, 96.8
	Mean (SD)	359.57 (302.292)	-73.29 (29.678)	1717.65 (1473.480)	36.09 (97.847)	333.68 (322.367)	-27.04 (74.186)
	95% CI of Mean	270.81, 448.33	-82.43, -64.15	1186.40, 2248.90	-1.13, 73.32	85.88, 581.48	-84.07, 29.99

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	67	30	21
	Missing, n (%)	8 (10.7)	5 (14.3)	3 (12.5)
	BLOQ, n (%)	1 (1.5)	4 (13.3)	1 (4.8)
	Geometric Mean (CV%)	2341.67 (103.877)	1462.77 (188.069)	1836.88 (137.729)
	95% CI of Geometric Mean	1900.63, 2885.06	924.16, 2315.27	1148.67, 2937.42
	Median	2248.02	2312.85	2470.32
	Q25, Q75	1314.14, 4607.88	711.99, 3314.45	1256.36, 4182.96
	Min, Max	262.5, 18776.1	144.8, 6973.1	201.7, 6392.2
	Mean (SD)	3254.56 (2853.550)	2442.70 (1951.606)	2666.63 (1888.323)
	95% CI of Mean	2558.52, 3950.60	1713.96, 3171.45	1807.07, 3526.19

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	4 (5.6)	2 (6.1)	3 (13.6)
	Geometric Mean (CV%)	622.76 (75.205)	1412.82 (196.811)	549.15 (91.491)
	95% CI of Geometric Mean	531.49, 729.70	904.24, 2207.43	388.62, 775.99
	Median	631.80	2473.04	570.32
	Q25, Q75	446.59, 1035.50	486.86, 3435.52	403.61, 1070.61
	Min, Max	131.0, 2762.5	103.0, 8175.0	103.8, 1529.2
	Mean (SD)	762.82 (488.439)	2428.23 (1999.594)	697.91 (436.559)
	95% CI of Mean	647.20, 878.43	1719.20, 3137.26	504.34, 891.47

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	30 (42.3)	7 (21.2)	10 (45.5)
	Geometric Mean (CV%)	197.08 (66.150)	1028.85 (302.291)	180.56 (57.652)
	95% CI of Geometric Mean	170.88, 227.29	599.76, 1764.91	142.38, 228.98
	Median	218.96	1829.77	169.34
	Q25, Q75	124.15, 291.55	264.88, 3336.08	117.80, 312.82
	Min, Max	52.9, 815.4	30.2, 8939.3	78.8, 432.5
	Mean (SD)	233.29 (137.428)	2138.51 (2087.706)	206.34 (106.994)
	95% CI of Mean	200.76, 265.83	1398.24, 2878.79	158.90, 253.78

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	33 (46.5)	5 (15.2)	12 (54.5)
	Geometric Mean (CV%)	175.69 (55.611)	1383.64 (278.186)	138.99 (49.275)
	95% CI of Geometric Mean	155.37, 198.66	820.90, 2332.14	113.03, 170.92
	Median	180.34	2651.04	128.04
	Q25, Q75	116.80, 244.40	324.29, 4216.85	99.75, 181.23
	Min, Max	66.4, 684.6	77.5, 8809.5	75.2, 369.6
	Mean (SD)	201.56 (115.975)	2718.53 (2267.736)	155.45 (82.671)
	95% CI of Mean	174.10, 229.01	1914.42, 3522.64	118.79, 192.11

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	30 (42.3)	3 (9.1)	8 (36.4)
	Geometric Mean (CV%)	215.34 (80.934)	1189.03 (253.201)	214.99 (63.645)
	95% CI of Geometric Mean	182.03, 254.74	719.86, 1963.98	166.00, 278.43
	Median	220.73	2314.65	211.75
	Q25, Q75	121.15, 376.90	255.36, 3833.44	143.90, 362.95
	Min, Max	40.6, 1983.5	95.2, 8379.3	77.8, 539.7
	Mean (SD)	279.39 (259.059)	2343.04 (2098.623)	251.10 (139.933)
	95% CI of Mean	218.07, 340.71	1598.90, 3087.19	189.05, 313.14

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	48 (67.6)	6 (18.2)	13 (59.1)
	Geometric Mean (CV%)	191.72 (54.744)	1246.41 (255.260)	156.74 (50.378)
	95% CI of Geometric Mean	169.83, 216.42	753.27, 2062.36	126.93, 193.53
	Median	192.50	2380.40	135.70
	Q25, Q75	137.40, 271.07	380.48, 3415.18	106.65, 227.81
	Min, Max	50.3, 1276.9	78.2, 10140.4	71.7, 466.0
	Mean (SD)	221.13 (155.787)	2469.48 (2338.716)	176.01 (95.544)
	95% CI of Mean	184.26, 258.01	1640.20, 3298.75	133.64, 218.38

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	37	29	12
	Missing, n (%)	3 (7.5)	5 (14.7)	1 (7.7)
	Geometric Mean (CV%)	2341.32 (118.413)	1609.24 (170.857)	1596.97 (174.643)
	95% CI of Geometric Mean	1713.58, 3199.02	1031.69, 2510.09	753.27, 3385.64
	Median	2188.12	2314.07	2549.42
	Q25, Q75	1287.40, 5179.87	823.61, 3314.45	832.56, 3576.84
	Min, Max	385.3, 18776.1	153.1, 6973.1	201.7, 6392.2
	Mean (SD)	3497.10 (3467.487)	2545.15 (1923.624)	2483.23 (1838.826)
	95% CI of Mean	2340.97, 4653.22	1813.44, 3276.87	1314.89, 3651.57

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Day 30	n	39	32	13
	Missing, n (%)	1 (2.5)	2 (5.9)	0
	BLOQ, n (%)	7 (17.9)	3 (9.4)	2 (15.4)
	Geometric Mean (CV%)	477.93 (125.841)	1699.49 (234.538)	510.16 (103.732)
	95% CI of Geometric Mean	348.49, 655.42	1037.74, 2783.24	304.37, 855.08
	Median	441.56	3441.32	425.32
	Q25, Q75	265.86, 1117.20	469.28, 4656.05	385.99, 865.70
	Min, Max	67.7, 2880.8	80.8, 6850.5	112.5, 2110.1
	Mean (SD)	733.06 (695.060)	2994.08 (2135.134)	708.54 (621.127)
	95% CI of Mean	507.74, 958.38	2224.28, 3763.89	333.19, 1083.89

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	37	30	11
	Missing, n (%)	2 (5.1)	5 (14.3)	1 (8.3)
	Geometric Mean (CV%)	2341.05 (111.489)	1592.24 (165.879)	1201.50 (173.314)
	95% CI of Geometric Mean	1734.86, 3159.05	1036.42, 2446.13	544.60, 2650.74
	Median	2137.25	2312.85	2034.45
	Q25, Q75	1287.40, 5179.87	823.61, 3314.45	408.76, 3397.20
	Min, Max	385.3, 18776.1	153.1, 6973.1	201.7, 4183.0
	Mean (SD)	3441.43 (3458.402)	2499.32 (1906.764)	1930.74 (1504.291)
	95% CI of Mean	2288.34, 4594.53	1787.32, 3211.32	920.14, 2941.34

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Day 60	n	39	33	11
	Missing, n (%)	0	2 (5.7)	1 (8.3)
	BLOQ, n (%)	8 (20.5)	4 (12.1)	3 (27.3)
	Geometric Mean (CV%)	399.49 (92.083)	1478.09 (254.256)	408.10 (161.310)
	95% CI of Geometric Mean	309.87, 515.02	894.06, 2443.63	190.75, 873.08
	Median	411.32	2442.18	464.27
	Q25, Q75	230.23, 583.39	516.46, 3493.45	168.38, 760.68
	Min, Max	75.7, 2855.1	45.3, 9121.1	87.0, 2694.2
	Mean (SD)	542.57 (514.119)	2752.01 (2376.440)	749.91 (937.680)
	95% CI of Mean	375.91, 709.24	1909.36, 3594.67	119.96, 1379.86

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	45	29	9
	Missing, n (%)	2 (4.3)	3 (9.4)	0
	Geometric Mean (CV%)	2352.13 (110.191)	1552.49 (168.987)	965.49 (177.211)
	95% CI of Geometric Mean	1799.41, 3074.61	997.97, 2415.12	386.22, 2413.58
	Median	2188.12	2311.64	1256.36
	Q25, Q75	1287.40, 5065.40	823.61, 3204.37	408.76, 2864.16
	Min, Max	385.3, 18776.1	153.1, 6973.1	201.7, 3756.5
	Mean (SD)	3399.90 (3239.727)	2471.21 (1934.179)	1620.54 (1431.750)
	95% CI of Mean	2426.57, 4373.22	1735.49, 3206.94	520.00, 2721.09

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1 Descriptive Statistics of MHBMA in 24-hour Urine Collection - PP Set**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Day 90	n	47	32	9
	BLOQ, n (%)	9 (19.1)	0	2 (22.2)
	Geometric Mean (CV%)	437.89 (98.610)	1727.90 (167.502)	415.96 (111.584)
	95% CI of Geometric Mean	343.77, 557.78	1138.94, 2621.42	208.37, 830.36
	Median	452.35	2685.99	420.00
	Q25, Q75	266.30, 750.38	627.31, 4016.72	351.20, 513.94
	Min, Max	78.9, 1850.3	139.1, 8355.8	69.4, 2331.1
	Mean (SD)	596.46 (473.947)	2777.08 (2204.508)	600.23 (664.942)
	95% CI of Mean	457.29, 735.62	1982.27, 3571.90	89.10, 1111.35

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.1 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Baseline	n	39	26	16	14	12	9
	Missing, n (%)	7 (15.2)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	BLOQ, n (%)	0	1 (3.8)	2 (12.5)	2 (14.3)	1 (8.3)	0
	Geometric Mean (CV%)	1375.87 (110.046)	1480.84 (111.067)	839.61 (153.597)	1027.67 (200.327)	809.37 (131.891)	1820.46 (108.406)
	95% CI of Geometric Mean	1030.80, 1836.46	1031.00, 2126.96	467.02, 1509.46	493.72, 2139.10	427.70, 1531.65	924.48, 3584.81
	Median	1244.93	1511.12	1268.18	1764.10	936.14	1742.21
	Q25, Q75	972.80, 2773.30	1049.44, 2500.00	446.12, 2000.16	252.78, 2649.80	321.88, 2172.10	1634.33, 2736.42
	Min, Max	155.7, 10792.9	174.8, 5934.6	96.3, 2759.7	167.2, 5519.7	125.0, 2613.4	231.3, 5922.7
	Mean (SD)	1958.07 (1846.941)	2065.73 (1656.924)	1245.76 (847.741)	1827.69 (1664.443)	1188.18 (935.578)	2344.80 (1573.385)
	95% CI of Mean	1359.35, 2556.78	1396.48, 2734.98	794.03, 1697.50	866.67, 2788.72	593.74, 1782.63	1135.38, 3554.21

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.1 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 1	n	42	29	18	15	13	9
	Missing, n (%)	4 (8.7)	0	2 (10.0)	0	2 (13.3)	0
	BLOQ, n (%)	1 (2.4)	3 (10.3)	1 (5.6)	1 (6.7)	2 (15.4)	1 (11.1)
	Geometric Mean (CV%)	356.69 (69.145)	430.62 (91.641)	783.62 (194.618)	1004.28 (162.170)	274.25 (93.349)	463.71 (87.606)
	95% CI of Geometric Mean	293.55, 433.40	319.96, 579.54	420.57, 1460.07	535.52, 1883.36	169.97, 442.49	259.60, 828.30
	Median	352.13	384.87	1289.39	1888.89	240.00	442.58
	Q25, Q75	255.12, 572.94	283.49, 742.86	256.62, 1892.31	365.14, 2431.82	161.74, 525.81	394.79, 564.24
	Min, Max	104.6, 1412.3	114.9, 4505.1	75.0, 3191.5	152.5, 3297.0	57.1, 951.1	92.6, 1368.4
	Mean (SD)	428.91 (270.881)	617.74 (800.211)	1324.54 (1045.072)	1556.92 (1110.923)	356.57 (258.713)	576.04 (387.302)
	95% CI of Mean	344.49, 513.32	313.35, 922.13	804.83, 1844.24	941.71, 2172.13	200.23, 512.92	278.33, 873.75

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.1 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 1	n	39	26	16	14	12	9
	Missing, n (%)	7 (15.2)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-76.01	-71.98	-12.93	-10.94	-74.34	-74.65
	Q25, Q75	-80.29, -66.81	-83.55, -54.46	-33.53, 17.51	-26.48, 0.00	-76.37, -62.01	-77.28, -70.24
	Min, Max	-86.9, 8.3	-89.9, 7.9	-50.9, 178.8	-51.2, 118.4	-82.8, 29.4	-88.4, -57.8
	Mean (SD)	-70.39 (17.898)	-63.82 (27.096)	13.12 (71.252)	-0.38 (44.452)	-61.58 (31.217)	-72.93 (9.510)
	95% CI of Mean	-76.19, -64.58	-74.77, -52.87	-24.86, 51.09	-26.05, 25.29	-81.42, -41.75	-80.25, -65.62

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.1 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 2	n	42	29	18	15	13	9
	Missing, n (%)	4 (8.7)	0	2 (10.0)	0	2 (13.3)	0
	BLOQ, n (%)	16 (38.1)	14 (48.3)	5 (27.8)	2 (13.3)	7 (53.8)	3 (33.3)
	Geometric Mean (CV%)	111.88 (69.652)	132.89 (71.044)	550.07 (371.020)	739.83 (230.021)	87.17 (57.758)	160.26 (67.999)
	95% CI of Geometric Mean	91.97, 136.11	104.20, 169.47	243.24, 1243.90	349.11, 1567.80	63.02, 120.55	99.77, 257.42
	Median	116.44	147.46	1164.95	1120.85	79.03	247.37
	Q25, Q75	69.74, 164.32	101.01, 173.58	85.62, 1646.09	230.91, 2002.22	58.14, 123.81	86.06, 263.26
	Min, Max	30.7, 460.5	29.1, 342.1	30.7, 4601.5	23.6, 2932.5	46.3, 261.3	74.3, 310.9
	Mean (SD)	134.85 (86.708)	157.71 (86.666)	1239.73 (1238.459)	1263.87 (974.139)	100.56 (61.573)	186.99 (98.817)
	95% CI of Mean	107.82, 161.87	124.74, 190.68	623.86, 1855.61	724.40, 1803.33	63.34, 137.77	111.03, 262.95

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.1 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 2	n	39	26	16	14	12	9
	Missing, n (%)	7 (15.2)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-92.23	-91.17	-23.39	-19.26	-93.56	-91.94
	Q25, Q75	-94.20, -88.93	-93.22, -88.53	-46.05, 15.16	-39.43, 0.00	-94.47, -74.02	-94.75, -89.45
	Min, Max	-97.8, -48.2	-98.8, 58.0	-88.9, 302.0	-86.5, 38.1	-97.6, -16.2	-95.3, -67.9
	Mean (SD)	-88.41 (10.698)	-83.06 (30.353)	0.42 (93.516)	-19.94 (34.997)	-80.31 (24.309)	-89.12 (8.846)
	95% CI of Mean	-91.88, -84.94	-95.33, -70.80	-49.41, 50.26	-40.15, 0.28	-95.76, -64.86	-95.92, -82.31

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.1 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 3	n	42	29	18	15	13	9
	Missing, n (%)	4 (8.7)	0	2 (10.0)	0	2 (13.3)	0
	BLOQ, n (%)	20 (47.6)	13 (44.8)	3 (16.7)	2 (13.3)	7 (53.8)	5 (55.6)
	Geometric Mean (CV%)	100.56 (61.892)	118.12 (49.086)	670.20 (284.591)	1146.85 (246.822)	86.68 (64.195)	95.05 (52.276)
	95% CI of Geometric Mean	84.20, 120.09	98.98, 140.96	320.09, 1403.25	528.31, 2489.59	60.78, 123.63	65.14, 138.69
	Median	93.81	123.53	1369.60	1964.79	85.52	89.47
	Q25, Q75	72.05, 141.15	79.74, 165.02	114.02, 1742.81	250.97, 3565.68	46.58, 133.09	65.10, 137.72
	Min, Max	33.3, 396.2	57.4, 268.0	56.1, 4235.8	104.0, 5332.6	45.5, 253.2	51.1, 226.5
	Mean (SD)	118.70 (77.280)	130.87 (59.854)	1325.46 (1157.529)	2119.16 (1704.234)	101.76 (61.604)	106.44 (57.247)
	95% CI of Mean	94.61, 142.79	108.10, 153.65	749.83, 1901.10	1175.38, 3062.94	64.53, 138.99	62.43, 150.45

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.1 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 3	n	39	26	16	14	12	9
	Missing, n (%)	7 (15.2)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-92.78	-92.15	-15.50	-3.59	-93.82	-95.84
	Q25, Q75	-95.39, -90.36	-94.32, -89.02	-40.08, 18.66	-22.22, 38.19	-96.48, -65.86	-96.35, -94.87
	Min, Max	-98.5, -65.4	-98.8, -19.9	-86.9, 270.1	-37.8, 107.2	-98.2, 19.8	-97.1, -64.8
	Mean (SD)	-90.52 (7.735)	-88.39 (14.967)	6.99 (83.039)	9.31 (46.456)	-74.01 (37.818)	-92.35 (10.371)
	95% CI of Mean	-93.03, -88.01	-94.44, -82.34	-37.26, 51.24	-17.52, 36.14	-98.05, -49.98	-100.33, -84.38

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.1 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 4	n	42	29	18	15	13	9
	Missing, n (%)	4 (8.7)	0	2 (10.0)	0	2 (13.3)	0
	BLOQ, n (%)	19 (45.2)	11 (37.9)	1 (5.6)	2 (13.3)	6 (46.2)	2 (22.2)
	Geometric Mean (CV%)	119.85 (100.853)	147.81 (68.813)	590.66 (258.107)	986.26 (263.246)	109.42 (67.166)	189.96 (67.699)
	95% CI of Geometric Mean	92.31, 155.60	116.64, 187.31	290.50, 1200.94	444.54, 2188.11	75.67, 158.21	118.47, 304.60
	Median	123.36	173.44	1314.81	1788.99	112.65	182.93
	Q25, Q75	56.95, 252.34	94.70, 211.62	131.19, 1651.58	351.61, 3180.33	69.44, 163.89	142.05, 250.00
	Min, Max	23.0, 1168.4	27.8, 376.7	49.5, 3262.2	70.6, 4308.3	42.4, 386.3	60.6, 465.7
	Mean (SD)	172.43 (188.917)	174.75 (97.258)	1128.31 (938.774)	1879.71 (1533.908)	130.80 (90.213)	222.54 (131.351)
	95% CI of Mean	113.56, 231.31	137.75, 211.75	661.46, 1595.15	1030.25, 2729.16	76.28, 185.32	121.57, 323.51

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.1 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 4	n	39	26	16	14	12	9
	Missing, n (%)	7 (15.2)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-92.12	-90.51	-11.16	-6.20	-91.27	-91.85
	Q25, Q75	-94.59, -84.05	-93.73, -82.03	-57.04, 21.73	-30.64, 33.16	-93.80, -75.83	-94.70, -83.78
	Min, Max	-99.2, 57.0	-98.6, -35.1	-79.0, 256.8	-72.1, 117.1	-96.3, 53.8	-96.9, 8.1
	Mean (SD)	-84.36 (26.552)	-82.59 (18.731)	-1.71 (80.444)	6.39 (53.284)	-68.18 (51.090)	-79.81 (33.344)
	95% CI of Mean	-92.97, -75.74	-90.16, -75.02	-44.58, 41.16	-24.38, 37.16	-100.64, -35.71	-105.44, -54.17

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.1 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 5	n	42	29	18	15	13	9
	Missing, n (%)	4 (8.7)	0	2 (10.0)	0	2 (13.3)	0
	BLOQ, n (%)	28 (66.7)	20 (69.0)	3 (16.7)	3 (20.0)	7 (53.8)	6 (66.7)
	Geometric Mean (CV%)	101.42 (66.131)	132.18 (47.495)	621.18 (266.373)	969.14 (259.535)	87.62 (57.688)	104.01 (45.292)
	95% CI of Geometric Mean	84.06, 122.37	111.34, 156.93	302.61, 1275.08	438.91, 2139.88	63.37, 121.14	74.62, 144.98
	Median	94.67	135.50	1319.98	1716.07	94.12	94.52
	Q25, Q75	73.10, 137.74	103.95, 171.46	128.45, 1629.46	182.28, 2979.07	50.56, 122.96	81.17, 144.08
	Min, Max	23.6, 686.5	46.7, 273.2	43.5, 4975.4	57.6, 4536.1	45.0, 200.0	51.1, 188.4
	Mean (SD)	124.12 (105.930)	144.71 (59.828)	1276.88 (1314.616)	1807.65 (1453.853)	100.08 (54.222)	112.82 (47.793)
	95% CI of Mean	91.10, 157.13	121.94, 167.47	623.13, 1930.63	1002.53, 2612.77	67.31, 132.85	76.08, 149.56

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.1 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 5	n	39	26	16	14	12	9
	Missing, n (%)	7 (15.2)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-92.67	-90.84	-15.93	-16.84	-90.83	-95.31
	Q25, Q75	-95.31, -87.49	-94.21, -87.05	-56.78, 19.21	-27.07, 6.24	-96.01, -77.74	-95.65, -93.97
	Min, Max	-98.8, -48.5	-97.7, -10.1	-67.6, 334.7	-66.9, 81.0	-98.2, 46.0	-97.0, -68.3
	Mean (SD)	-88.39 (12.252)	-86.21 (17.620)	8.20 (100.348)	-4.51 (41.248)	-74.60 (41.769)	-92.20 (9.073)
	95% CI of Mean	-92.37, -84.42	-93.33, -79.09	-45.27, 61.68	-28.33, 19.31	-101.14, -48.05	-99.18, -85.22

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.1 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=28)	Females (N=19)	Males (N=19)	Females (N=13)	Males (N=7)	Females (N=2)
Baseline	n	26	17	17	12	7	2
	Missing, n (%)	2 (7.1)	2 (10.5)	2 (10.5)	1 (7.7)	0	0
	Geometric Mean (CV%)	1433.30 (129.596)	1423.27 (109.416)	849.12 (145.634)	1110.66 (194.199)	390.88 (105.764)	2594.83 (7.524)
	95% CI of Geometric Mean	959.81, 2140.38	901.93, 2245.95	490.62, 1469.56	501.93, 2457.65	175.39, 871.09	1321.08, 5096.68
	Median	1537.55	1340.63	1144.55	1764.10	311.95	2598.49
	Q25, Q75	688.37, 3070.45	1015.42, 2451.13	495.41, 1970.87	345.03, 2902.64	163.24, 1025.41	2460.57, 2736.42
	Min, Max	155.7, 10792.9	316.3, 5934.6	96.3, 2759.7	167.2, 5519.7	125.0, 1195.2	2460.6, 2736.4
	Mean (SD)	2171.16 (2145.807)	2030.10 (1817.560)	1232.29 (822.700)	1924.62 (1730.785)	529.84 (425.379)	2598.49 (195.056)
	95% CI of Mean	1304.44, 3037.87	1095.60, 2964.61	809.29, 1655.29	824.93, 3024.31	136.42, 923.25	845.98, 4351.01

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.1 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=28)	Females (N=19)	Males (N=19)	Females (N=13)	Males (N=7)	Females (N=2)
Day 90	n	28	19	19	13	7	2
	BLOQ, n (%)	4 (14.3)	5 (26.3)	0	0	2 (28.6)	0
	Geometric Mean (CV%)	268.64 (94.041)	250.08 (106.145)	868.63 (192.419)	1355.34 (152.854)	224.05 (118.533)	322.88 (27.820)
	95% CI of Geometric Mean	197.29, 365.78	164.53, 380.11	476.85, 1582.28	698.18, 2631.04	94.20, 532.85	27.77, 3753.27
	Median	290.54	223.20	1176.77	1941.27	206.73	328.92
	Q25, Q75	139.10, 445.29	126.90, 563.52	280.20, 2046.98	709.01, 2857.14	110.62, 373.64	266.20, 391.64
	Min, Max	69.3, 1359.2	62.3, 1049.9	55.4, 4243.2	171.2, 6715.6	60.2, 1141.2	266.2, 391.6
	Mean (SD)	361.68 (300.964)	356.45 (312.478)	1463.83 (1213.907)	2088.61 (1774.078)	335.04 (370.458)	328.92 (88.706)
	95% CI of Mean	244.98, 478.39	205.84, 507.07	878.74, 2048.92	1016.54, 3160.68	-7.58, 677.66	-468.08, 1125.92

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.1 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=28)	Females (N=19)	Males (N=19)	Females (N=13)	Males (N=7)	Females (N=2)
%Change from baseline to Day 90	n	26	17	17	12	7	2
	Missing, n (%)	2 (7.1)	2 (10.5)	2 (10.5)	1 (7.7)	0	0
	Median	-78.40	-88.60	-9.26	2.96	-11.50	-87.43
	Q25, Q75	-92.55, -65.10	-89.55, -66.47	-29.39, 61.29	-5.02, 29.56	-80.45, 72.36	-89.18, -85.69
	Min, Max	-95.9, 68.3	-97.8, -20.8	-50.9, 270.7	-39.8, 324.0	-85.7, 96.8	-89.2, -85.7
	Mean (SD)	-70.71 (34.228)	-77.23 (21.309)	37.93 (101.141)	33.50 (97.358)	-9.79 (75.987)	-87.43 (2.471)
	95% CI of Mean	-84.54, -56.88	-88.19, -66.27	-14.08, 89.94	-28.37, 95.36	-80.07, 60.49	-109.64, -65.23

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.2 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Baseline	n	37	28	17	13	11	10
	Missing, n (%)	6 (14.0)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	BLOQ, n (%)	1 (2.7)	0	2 (11.8)	2 (15.4)	1 (9.1)	0
	Geometric Mean (CV%)	1260.36 (92.416)	1654.08 (130.784)	1186.91 (154.570)	663.76 (180.832)	989.12 (137.631)	1346.39 (137.536)
	95% CI of Geometric Mean	969.87, 1637.83	1123.04, 2436.21	672.54, 2094.66	320.48, 1374.71	494.85, 1977.07	644.22, 2813.88
	Median	1244.93	1934.82	1527.03	437.28	1566.82	1688.27
	Q25, Q75	1015.42, 2202.80	867.32, 3337.72	868.90, 2042.01	179.86, 2260.27	311.95, 2427.42	579.88, 2613.43
	Min, Max	155.7, 4109.6	233.6, 10792.9	96.3, 5519.7	167.2, 2759.7	125.0, 2736.4	231.3, 5922.7
	Mean (SD)	1613.36 (1054.535)	2513.56 (2321.330)	1777.86 (1431.836)	1176.63 (1074.631)	1404.85 (938.198)	1990.80 (1690.233)
	95% CI of Mean	1261.75, 1964.96	1613.43, 3413.68	1041.68, 2514.05	527.24, 1826.03	774.56, 2035.15	781.68, 3199.93

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.2 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Day 1	n	40	31	19	14	12	10
	Missing, n (%)	3 (7.0)	1 (3.1)	1 (5.0)	1 (6.7)	1 (7.7)	1 (9.1)
	BLOQ, n (%)	2 (5.0)	2 (6.5)	1 (5.3)	1 (7.1)	1 (8.3)	2 (20.0)
	Geometric Mean (CV%)	340.35 (67.206)	451.95 (89.865)	995.01 (162.785)	739.24 (202.278)	341.41 (69.255)	338.28 (133.783)
	95% CI of Geometric Mean	279.97, 413.73	340.82, 599.33	574.97, 1721.90	353.90, 1544.17	229.38, 508.16	163.90, 698.17
	Median	352.13	472.05	1808.12	955.17	418.68	398.83
	Q25, Q75	207.27, 528.82	268.14, 751.87	559.57, 2261.90	185.85, 2729.93	210.10, 545.02	159.05, 638.64
	Min, Max	104.6, 1168.5	114.9, 4505.1	75.0, 3191.5	120.9, 3297.0	113.4, 951.1	57.1, 1368.4
	Mean (SD)	404.72 (241.695)	636.76 (781.686)	1480.91 (950.375)	1361.30 (1237.670)	403.81 (237.357)	497.41 (420.562)
	95% CI of Mean	327.42, 482.03	350.04, 923.49	1022.83, 1938.98	646.69, 2075.92	253.00, 554.62	196.56, 798.27

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.2 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
%Change from baseline to Day 1	n	37	28	17	13	11	10
	Missing, n (%)	6 (14.0)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-76.01	-73.59	-22.99	-7.01	-74.17	-74.58
	Q25, Q75	-79.91, -65.65	-83.24, -54.74	-36.02, 16.61	-15.60, 7.40	-76.59, -60.82	-76.90, -70.24
	Min, Max	-89.3, 8.3	-89.9, 0.0	-51.2, 178.8	-32.0, 118.4	-79.4, 29.4	-88.4, -57.8
	Mean (SD)	-69.35 (20.863)	-65.66 (23.815)	7.05 (71.572)	6.51 (42.068)	-60.18 (32.297)	-73.34 (9.231)
	95% CI of Mean	-76.31, -62.39	-74.90, -56.42	-29.75, 43.86	-18.92, 31.94	-81.88, -38.48	-79.95, -66.74

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.2 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Day 2	n	40	31	19	14	12	10
	Missing, n (%)	3 (7.0)	1 (3.1)	1 (5.0)	1 (6.7)	1 (7.7)	1 (9.1)
	BLOQ, n (%)	18 (45.0)	12 (38.7)	4 (21.1)	3 (21.4)	7 (58.3)	3 (30.0)
	Geometric Mean (CV%)	110.40 (66.918)	133.71 (73.966)	746.83 (263.474)	498.99 (350.496)	104.09 (77.495)	121.86 (64.833)
	95% CI of Geometric Mean	90.87, 134.11	104.94, 170.38	373.16, 1494.65	197.15, 1262.93	67.32, 160.95	79.77, 186.18
	Median	110.05	144.51	1120.85	842.63	93.12	100.80
	Q25, Q75	68.16, 168.08	95.69, 173.58	610.40, 1824.00	206.71, 1857.92	58.17, 214.39	79.03, 247.37
	Min, Max	35.5, 283.3	29.1, 460.5	35.7, 4601.5	23.6, 3477.2	46.3, 263.5	57.1, 310.9
	Mean (SD)	130.75 (74.735)	161.53 (98.853)	1353.14 (1143.088)	1111.68 (1087.504)	129.20 (88.450)	143.98 (91.950)
	95% CI of Mean	106.84, 154.66	125.26, 197.79	802.18, 1904.09	483.77, 1739.59	73.00, 185.40	78.19, 209.76

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.2 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
%Change from baseline to Day 2	n	37	28	17	13	11	10
	Missing, n (%)	6 (14.0)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-91.87	-92.36	-19.86	-20.29	-93.10	-92.98
	Q25, Q75	-93.22, -88.93	-94.63, -86.55	-50.83, 4.32	-32.91, 0.00	-94.53, -66.34	-94.75, -82.80
	Min, Max	-97.8, 58.0	-98.8, -55.3	-88.9, 302.0	-86.5, 38.1	-97.6, -16.2	-95.3, -67.9
	Mean (SD)	-85.19 (25.834)	-87.71 (11.707)	-1.36 (90.052)	-19.17 (38.847)	-79.89 (25.321)	-88.70 (8.862)
	95% CI of Mean	-93.81, -76.57	-92.25, -83.16	-47.66, 44.95	-42.65, 4.31	-96.91, -62.87	-95.05, -82.36

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.2 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Day 3	n	40	31	19	14	12	10
	Missing, n (%)	3 (7.0)	1 (3.1)	1 (5.0)	1 (6.7)	1 (7.7)	1 (9.1)
	BLOQ, n (%)	19 (47.5)	14 (45.2)	3 (15.8)	2 (14.3)	7 (58.3)	5 (50.0)
	Geometric Mean (CV%)	104.61 (57.803)	111.10 (57.154)	1028.38 (281.416)	666.52 (257.542)	95.11 (58.449)	84.25 (60.483)
	95% CI of Geometric Mean	88.10, 124.21	91.41, 135.02	504.08, 2097.97	292.63, 1518.09	67.39, 134.23	56.50, 125.62
	Median	102.59	116.55	1655.09	709.84	106.99	85.45
	Q25, Q75	77.89, 143.33	69.44, 165.02	1103.00, 2437.57	179.86, 3195.63	58.11, 138.69	46.58, 133.09
	Min, Max	33.3, 396.2	42.4, 340.1	56.1, 5332.6	104.0, 3586.8	46.3, 253.2	45.5, 226.5
	Mean (SD)	120.75 (71.610)	127.44 (69.985)	1875.54 (1487.632)	1429.32 (1445.257)	108.78 (60.209)	97.54 (58.982)
	95% CI of Mean	97.85, 143.66	101.76, 153.11	1158.52, 2592.56	594.85, 2263.79	70.52, 147.04	55.34, 139.74

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.2 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
%Change from baseline to Day 3	n	37	28	17	13	11	10
	Missing, n (%)	6 (14.0)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-92.25	-93.60	-9.96	-20.96	-94.76	-95.52
	Q25, Q75	-94.17, -88.88	-95.69, -89.62	-22.22, 18.68	-35.88, 18.64	-96.48, -54.68	-96.47, -86.30
	Min, Max	-98.5, -19.9	-98.8, -65.4	-86.9, 270.1	-52.5, 107.2	-97.5, 19.8	-98.2, -64.8
	Mean (SD)	-88.38 (13.306)	-91.37 (7.274)	12.75 (78.669)	1.95 (51.354)	-74.36 (39.908)	-90.14 (11.018)
	95% CI of Mean	-92.82, -83.94	-94.20, -88.55	-27.70, 53.21	-29.09, 32.99	-101.18, -47.55	-98.02, -82.25

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.2 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Day 4	n	40	31	19	14	12	10
	Missing, n (%)	3 (7.0)	1 (3.1)	1 (5.0)	1 (6.7)	1 (7.7)	1 (9.1)
	BLOQ, n (%)	20 (50.0)	10 (32.3)	1 (5.3)	2 (14.3)	5 (41.7)	3 (30.0)
	Geometric Mean (CV%)	117.50 (95.414)	149.59 (77.508)	942.61 (217.918)	542.50 (324.902)	139.65 (79.816)	134.14 (71.003)
	95% CI of Geometric Mean	90.84, 151.99	116.31, 192.39	498.31, 1783.04	219.85, 1338.67	89.39, 218.16	84.93, 211.87
	Median	107.40	173.44	1460.18	418.87	147.33	134.66
	Q25, Q75	62.23, 216.52	82.64, 291.50	505.00, 1788.99	105.96, 3079.21	80.47, 202.47	112.65, 182.93
	Min, Max	23.0, 1168.4	25.6, 377.4	49.5, 4308.3	70.4, 3266.2	47.6, 465.7	42.4, 399.0
	Mean (SD)	166.39 (188.074)	182.40 (107.120)	1574.92 (1193.300)	1327.26 (1425.481)	175.33 (129.560)	159.93 (102.474)
	95% CI of Mean	106.24, 226.54	143.11, 221.70	999.76, 2150.08	504.21, 2150.32	93.01, 257.65	86.62, 233.24

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.2 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
%Change from baseline to Day 4	n	37	28	17	13	11	10
	Missing, n (%)	6 (14.0)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-91.32	-91.64	-12.39	0.00	-91.45	-91.46
	Q25, Q75	-94.11, -83.70	-94.68, -82.43	-34.90, 20.54	-60.41, 33.16	-94.38, -64.42	-94.70, -87.23
	Min, Max	-97.5, -22.7	-99.2, 57.0	-73.5, 256.8	-79.0, 117.1	-96.3, 53.8	-96.9, 8.1
	Mean (SD)	-85.74 (15.510)	-80.88 (31.372)	4.76 (72.838)	-1.44 (64.096)	-65.62 (52.856)	-81.46 (31.711)
	95% CI of Mean	-90.92, -80.57	-93.05, -68.71	-32.70, 42.21	-40.17, 37.30	-101.13, -30.10	-104.15, -58.77

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.2 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Day 5	n	40	31	19	14	12	10
	Missing, n (%)	3 (7.0)	1 (3.1)	1 (5.0)	1 (6.7)	1 (7.7)	1 (9.1)
	BLOQ, n (%)	26 (65.0)	22 (71.0)	3 (15.8)	3 (21.4)	8 (66.7)	5 (50.0)
	Geometric Mean (CV%)	111.53 (66.421)	114.95 (53.313)	938.68 (219.144)	571.27 (329.890)	97.98 (52.183)	89.41 (55.304)
	95% CI of Geometric Mean	91.92, 135.32	95.68, 138.11	495.39, 1778.61	230.32, 1416.91	71.73, 133.83	61.79, 129.39
	Median	114.36	125.00	1530.86	874.68	94.32	88.33
	Q25, Q75	81.11, 159.79	79.19, 171.46	429.16, 2495.18	128.45, 2901.72	71.01, 147.04	51.12, 144.08
	Min, Max	23.6, 686.5	45.9, 261.8	43.5, 4975.4	57.6, 3343.3	45.0, 200.0	45.9, 188.4
	Mean (SD)	135.24 (107.743)	129.03 (61.687)	1648.94 (1437.395)	1340.62 (1339.348)	109.03 (51.770)	100.80 (52.246)
	95% CI of Mean	100.77, 169.70	106.40, 151.66	956.14, 2341.75	567.30, 2113.94	76.13, 141.93	63.42, 138.18

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.2 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
%Change from baseline to Day 5	n	37	28	17	13	11	10
	Missing, n (%)	6 (14.0)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-91.68	-93.14	-15.96	-17.71	-94.93	-94.04
	Q25, Q75	-94.33, -86.42	-95.38, -88.09	-33.23, 13.90	-43.16, 21.15	-95.65, -72.87	-96.87, -84.76
	Min, Max	-97.8, -10.1	-98.8, -50.1	-66.0, 334.7	-67.6, 81.0	-98.2, 46.0	-98.2, -68.3
	Mean (SD)	-86.39 (16.534)	-89.01 (11.531)	10.20 (94.576)	-8.11 (48.977)	-74.67 (44.010)	-90.36 (9.343)
	95% CI of Mean	-91.91, -80.88	-93.48, -84.53	-38.43, 58.84	-37.71, 21.50	-104.25, -45.10	-97.05, -83.67

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.2 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=26)	>19 cig/day (N=21)	10-19 cig/day (N=13)	>19 cig/day (N=19)	10-19 cig/day (N=3)	>19 cig/day (N=6)
Baseline	n	19	24	17	12	6	3
	Missing, n (%)	2 (9.5)	2 (7.7)	2 (10.5)	1 (7.7)	0	0
	Geometric Mean (CV%)	1195.08 (101.140)	1646.92 (133.179)	1186.91 (154.570)	691.08 (163.573)	420.20 (171.451)	1194.73 (82.813)
	95% CI of Geometric Mean	797.43, 1791.01	1075.09, 2522.89	672.54, 2094.66	334.73, 1426.78	122.96, 1435.88	198.43, 7193.04
	Median	1234.13	1833.21	1527.03	726.99	310.07	1195.19
	Q25, Q75	636.66, 2500.00	867.32, 3337.72	868.90, 2042.01	215.31, 2033.85	163.24, 1025.41	579.88, 2460.57
	Min, Max	155.7, 4109.6	233.6, 10792.9	96.3, 5519.7	167.2, 2759.7	125.0, 2736.4	579.9, 2460.6
	Mean (SD)	1577.66 (1101.663)	2541.10 (2435.998)	1777.86 (1431.836)	1151.72 (1026.582)	778.37 (1013.793)	1411.88 (958.886)
	95% CI of Mean	1046.67, 2108.65	1512.46, 3569.73	1041.68, 2514.05	499.46, 1803.99	-285.55, 1842.28	-970.13, 3793.89

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.2 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=26)	>19 cig/day (N=21)	10-19 cig/day (N=13)	>19 cig/day (N=19)	10-19 cig/day (N=3)	>19 cig/day (N=6)
Day 90	n	21	26	19	13	6	3
	BLOQ, n (%)	3 (14.3)	6 (23.1)	0	0	2 (33.3)	0
	Geometric Mean (CV%)	267.82 (108.353)	255.58 (91.434)	1107.84 (166.343)	949.84 (205.072)	196.01 (85.590)	373.46 (129.452)
	95% CI of Geometric Mean	179.32, 400.00	186.54, 350.16	635.93, 1929.94	437.08, 2064.11	90.03, 426.75	31.76, 4390.94
	Median	306.00	246.54	1521.43	2046.98	244.04	266.20
	Q25, Q75	142.69, 517.77	130.28, 445.69	646.91, 2033.49	280.20, 2870.04	110.62, 373.64	171.46, 1141.24
	Min, Max	62.3, 1359.2	69.3, 1049.9	55.4, 6715.6	104.7, 3362.9	60.2, 391.6	171.5, 1141.2
	Mean (SD)	381.54 (338.863)	341.82 (274.854)	1758.57 (1600.649)	1657.83 (1326.329)	237.37 (136.150)	526.30 (534.659)
	95% CI of Mean	227.29, 535.79	230.80, 452.84	987.08, 2530.07	856.34, 2459.33	94.49, 380.26	-801.87, 1854.47

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.1.2 Descriptive Statistics of MHBMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=26)	>19 cig/day (N=21)	10-19 cig/day (N=13)	>19 cig/day (N=19)	10-19 cig/day (N=3)	>19 cig/day (N=6)
%Change from baseline to Day 90	n	19	24	17	12	6	3
	Missing, n (%)	2 (9.5)	2 (7.7)	2 (10.5)	1 (7.7)	0	0
	Median	-77.59	-88.22	-5.11	2.96	-45.67	-85.65
	Q25, Q75	-88.92, -64.77	-91.73, -67.21	-33.55, 46.10	-6.33, 63.49	-80.45, 19.78	-89.18, 96.81
	Min, Max	-94.4, -18.5	-97.8, 68.3	-50.9, 270.7	-41.1, 324.0	-85.7, 72.4	-89.2, 96.8
	Mean (SD)	-73.03 (20.814)	-73.49 (35.626)	28.47 (94.108)	46.90 (106.166)	-27.56 (65.409)	-26.01 (106.376)
	95% CI of Mean	-83.07, -63.00	-88.54, -58.44	-19.92, 76.86	-20.56, 114.36	-96.21, 41.09	-290.27, 238.25

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	69		36		36	
	Missing, n (%)	11 (13.8)		5 (12.2)		3 (7.7)	
	BLOQ, n (%)	1 (1.4)		4 (11.1)		1 (2.8)	
	Geometric Mean (CV%)	1446.33 (106.240)		1058.89 (164.481)		1183.90 (129.677)	
	95% CI of Geometric Mean	1173.77, 1782.18		718.91, 1559.64		846.00, 1656.76	
	Median	1434.51		1552.46		1443.79	
	Q25, Q75	1015.42, 2764.71		466.34, 2268.58		713.38, 2455.64	
	Min, Max	155.7, 10792.9		96.3, 5917.3		125.0, 5922.7	
	Mean (SD)	2010.81 (1719.781)		1710.05 (1465.888)		1756.95 (1474.057)	
	95% CI of Mean	1597.67, 2423.96		1214.06, 2206.04		1258.20, 2255.70	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	4 (5.3)		2 (5.1)		3 (8.1)	
	Geometric Mean (CV%)	385.41 (76.620)		1010.13 (172.894)		402.55 (129.895)	
	95% CI of Geometric Mean	329.62, 450.65		689.88, 1479.02		288.97, 560.78	
	Median	370.81	-76.01	1769.50	-10.22	441.63	-73.37
	Q25, Q75	255.12, 634.03	-80.59, -63.93	380.37, 2299.27	-27.40, 14.27	201.48, 849.41	-76.93, -46.77
	Min, Max	104.6, 4505.1	-89.9, 8.3	75.0, 6623.1	-51.2, 178.8	57.1, 4858.4	-89.0, 29.4
	Mean (SD)	501.07 (541.070)	-68.47 (21.650)	1645.44 (1364.245)	7.11 (56.143)	668.15 (879.352)	-57.76 (31.420)
	95% CI of Mean	376.57, 625.56	-73.67, -63.26	1203.20, 2087.68	-11.89, 26.12	374.95, 961.35	-68.39, -47.12

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	31 (41.3)		7 (17.9)		13 (35.1)	
	Geometric Mean (CV%)	123.14 (70.614)		769.64 (286.360)		160.62 (170.464)	
	95% CI of Geometric Mean	106.37, 142.55		474.86, 1247.43		108.84, 237.05	
	Median	136.36	-91.87	1413.04	-17.43	137.07	-87.91
	Q25, Q75	80.71, 173.58	-93.54, -88.93	286.58, 1898.27	-32.36, 12.63	74.29, 259.62	-94.64, -65.70
	Min, Max	29.1, 460.5	-98.8, 58.0	23.6, 6790.5	-88.9, 302.0	24.5, 4858.4	-97.9, 0.0
	Mean (SD)	147.87 (87.791)	-86.49 (20.261)	1525.69 (1479.823)	-5.24 (67.259)	415.73 (909.604)	-72.15 (33.812)
	95% CI of Mean	127.67, 168.08	-91.36, -81.61	1045.98, 2005.40	-28.00, 17.53	112.45, 719.01	-83.59, -60.70

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	34 (45.3)		5 (12.8)		20 (54.1)	
	Geometric Mean (CV%)	108.65 (57.770)		970.18 (250.857)		127.58 (180.646)	
	95% CI of Geometric Mean	96.03, 122.94		614.34, 1532.14		85.39, 190.61	
	Median	106.16	-92.66	1651.82	-8.18	89.93	-93.81
	Q25, Q75	73.17, 158.97	-95.13, -89.28	250.97, 3195.63	-28.21, 18.66	51.12, 149.70	-96.41, -69.19
	Min, Max	33.3, 396.2	-98.8, -19.9	56.1, 7514.8	-86.9, 270.1	30.1, 4858.4	-98.2, 19.8
	Mean (SD)	125.27 (70.612)	-89.86 (10.850)	1863.75 (1707.882)	5.85 (62.208)	384.92 (917.788)	-72.72 (37.825)
	95% CI of Mean	109.02, 141.52	-92.47, -87.25	1310.11, 2417.39	-15.20, 26.90	78.91, 690.93	-85.52, -59.92

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	30 (40.0)		3 (7.7)		10 (27.0)	
	Geometric Mean (CV%)	136.33 (88.890)		893.06 (250.752)		214.54 (146.306)	
	95% CI of Geometric Mean	114.37, 162.50		565.55, 1410.22		150.17, 306.49	
	Median	141.71	-90.53	1460.18	1.68	182.93	-87.50
	Q25, Q75	74.85, 254.92	-94.35, -82.44	351.61, 2842.86	-35.95, 24.33	117.79, 348.31	-93.47, -1.03
	Min, Max	23.0, 1168.4	-99.2, 57.0	49.5, 7302.0	-79.0, 256.8	42.4, 4858.4	-96.9, 53.8
	Mean (SD)	180.22 (156.351)	-83.74 (22.896)	1711.28 (1564.027)	4.28 (62.540)	460.38 (898.147)	-60.74 (45.945)
	95% CI of Mean	144.25, 216.20	-89.24, -78.23	1204.27, 2218.28	-16.89, 25.45	160.92, 759.85	-76.29, -45.19

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	51 (68.0)		6 (15.4)		21 (56.8)	
	Geometric Mean (CV%)	114.22 (59.388)		863.80 (247.685)		140.35 (164.181)	
	95% CI of Geometric Mean	100.64, 129.62		548.36, 1360.70		95.86, 205.48	
	Median	116.82	-92.67	1530.86	-15.36	94.52	-92.56
	Q25, Q75	80.39, 168.78	-94.51, -87.49	240.25, 2726.97	-38.19, 13.74	71.74, 177.28	-95.40, -68.62
	Min, Max	23.6, 686.5	-98.8, -10.1	43.5, 6359.6	-67.6, 334.7	45.0, 4858.4	-98.2, 46.0
	Mean (SD)	133.24 (88.428)	-87.83 (14.176)	1683.02 (1572.357)	-0.32 (71.464)	391.44 (915.462)	-71.67 (39.224)
	95% CI of Mean	112.89, 153.59	-91.24, -84.42	1173.32, 2192.73	-24.51, 23.87	86.20, 696.67	-84.94, -58.39

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	10 (13.3)		4 (10.3)		2 (5.4)	
	Geometric Mean (CV%)	338.13 (113.025)		1089.76 (223.167)		449.60 (119.354)	
	95% CI of Geometric Mean	274.43, 416.63		706.41, 1681.14		328.51, 615.31	
	Median	328.70	-75.95	2064.52	17.48	489.36	-64.09
	Q25, Q75	171.90, 713.35	-87.05, -53.41	303.13, 2787.06	-18.48, 55.78	243.57, 888.26	-82.71, 0.00
	Min, Max	53.9, 2150.9	-98.5, 22.9	31.4, 4646.6	-82.3, 172.7	53.2, 4858.4	-95.5, 116.1
	Mean (SD)	500.93 (474.915)	-65.31 (30.161)	1880.48 (1380.142)	22.76 (58.034)	706.28 (870.981)	-43.58 (50.349)
	95% CI of Mean	391.66, 610.21	-72.56, -58.06	1433.08, 2327.87	3.11, 42.40	415.88, 996.69	-60.62, -26.54

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	12 (16.0)		5 (12.8)		4 (10.8)	
	Geometric Mean (CV%)	315.04 (115.045)		964.17 (223.603)		480.50 (154.071)	
	95% CI of Geometric Mean	255.04, 389.16		624.75, 1487.99		332.67, 694.03	
	Median	329.73	-77.82	1464.97	-5.56	476.67	-54.81
	Q25, Q75	157.23, 589.36	-89.90, -56.44	411.72, 2624.52	-37.84, 34.21	260.71, 1070.97	-79.58, 0.00
	Min, Max	41.3, 3893.4	-98.4, 161.9	28.2, 5838.9	-59.6, 208.8	52.4, 4858.4	-96.0, 189.2
	Mean (SD)	475.86 (540.655)	-64.61 (42.298)	1709.53 (1436.598)	10.33 (63.861)	820.85 (929.669)	-37.03 (62.091)
	95% CI of Mean	351.46, 600.26	-74.78, -54.44	1243.84, 2175.23	-11.28, 31.94	510.88, 1130.82	-58.04, -16.01

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	15 (20.0)		1 (2.6)		3 (8.1)	
	Geometric Mean (CV%)	302.04 (122.847)		1145.00 (174.805)		526.17 (127.748)	
	95% CI of Geometric Mean	242.23, 376.63		780.23, 1680.31		379.03, 730.43	
	Median	306.00	-80.19	1898.50	-0.04	512.48	-58.06
	Q25, Q75	142.69, 563.52	-89.55, -58.85	463.54, 2825.00	-23.73, 39.99	293.49, 1070.97	-79.02, -3.17
	Min, Max	50.9, 6415.4	-97.8, 99.1	55.4, 6715.6	-50.9, 324.0	60.2, 4858.4	-89.2, 96.8
	Mean (SD)	505.07 (803.507)	-67.26 (37.776)	1866.73 (1536.281)	30.74 (88.790)	822.12 (905.289)	-41.37 (45.949)
	95% CI of Mean	320.19, 689.94	-76.34, -58.18	1368.72, 2364.74	0.70, 60.79	520.27, 1123.96	-56.92, -25.82

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	71	36	36
	Missing, n (%)	9 (11.3)	5 (12.2)	3 (7.7)
	BLOQ, n (%)	1 (1.4)	4 (11.1)	1 (2.8)
	Geometric Mean (CV%)	2392.31 (101.027)	1692.38 (180.617)	1937.41 (137.112)
	95% CI of Geometric Mean	1961.56, 2917.65	1126.07, 2543.49	1368.02, 2743.80
	Median	2285.01	2339.10	2230.33
	Q25, Q75	1590.30, 4607.88	951.05, 3850.99	1293.66, 4046.67
	Min, Max	262.5, 18776.1	144.8, 9531.1	201.7, 12655.0
	Mean (SD)	3273.24 (2783.288)	2790.45 (2351.252)	2947.51 (2713.836)
	95% CI of Mean	2614.44, 3932.04	1994.89, 3586.00	2029.28, 3865.75

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 1	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n (%)	4 (5.3)	2 (5.1)	3 (8.1)
	Geometric Mean (CV%)	622.07 (72.750)	1625.55 (191.236)	669.92 (125.007)
	95% CI of Geometric Mean	535.44, 722.71	1087.39, 2430.06	484.79, 925.75
	Median	619.25	2523.48	655.32
	Q25, Q75	455.20, 1035.12	584.10, 3605.30	350.87, 1272.25
	Min, Max	131.0, 2762.5	103.0, 9603.4	103.8, 10831.8
	Mean (SD)	754.89 (476.556)	2772.06 (2404.326)	1139.02 (1808.735)
	95% CI of Mean	645.24, 864.54	1992.66, 3551.46	535.96, 1742.09

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 2	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n (%)	31 (41.3)	7 (17.9)	13 (35.1)
	Geometric Mean (CV%)	201.55 (65.510)	1256.29 (294.963)	264.73 (163.628)
	95% CI of Geometric Mean	175.66, 231.26	770.69, 2047.87	180.94, 387.29
	Median	227.26	1978.79	211.83
	Q25, Q75	126.65, 308.72	472.10, 3414.30	123.80, 332.33
	Min, Max	52.9, 815.4	30.2, 10409.0	64.3, 10831.8
	Mean (SD)	237.54 (136.361)	2590.45 (2665.029)	734.28 (1874.333)
	95% CI of Mean	206.16, 268.92	1726.55, 3454.36	109.34, 1359.22

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 3	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n (%)	34 (45.3)	5 (12.8)	20 (54.1)
	Geometric Mean (CV%)	177.51 (55.137)	1561.38 (253.548)	202.97 (181.098)
	95% CI of Geometric Mean	157.66, 199.85	986.61, 2470.99	135.77, 303.41
	Median	184.80	2570.99	152.10
	Q25, Q75	117.30, 247.82	482.63, 4410.51	99.75, 221.99
	Min, Max	66.4, 684.6	77.5, 8809.5	61.8, 10831.8
	Mean (SD)	203.06 (114.659)	2939.10 (2504.671)	682.99 (1887.684)
	95% CI of Mean	176.68, 229.45	2127.17, 3751.02	53.60, 1312.38

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 4	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n (%)	30 (40.0)	3 (7.7)	10 (27.0)
	Geometric Mean (CV%)	223.86 (81.028)	1433.54 (246.660)	343.77 (147.653)
	95% CI of Geometric Mean	190.10, 263.62	910.79, 2256.30	240.16, 492.06
	Median	241.28	2388.30	296.66
	Q25, Q75	121.25, 383.44	401.86, 4229.60	170.15, 456.30
	Min, Max	40.6, 1983.5	95.2, 11251.3	77.8, 10831.8
	Mean (SD)	288.50 (255.340)	2763.61 (2580.056)	803.78 (1858.037)
	95% CI of Mean	229.74, 347.25	1927.25, 3599.98	184.27, 1423.29

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 5	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n (%)	51 (68.0)	6 (15.4)	21 (56.8)
	Geometric Mean (CV%)	193.54 (54.349)	1424.30 (243.725)	238.04 (164.445)
	95% CI of Geometric Mean	172.16, 217.58	907.08, 2236.42	162.53, 348.62
	Median	192.50	2380.40	185.59
	Q25, Q75	137.40, 274.35	383.68, 3564.95	113.30, 270.22
	Min, Max	50.3, 1276.9	78.2, 10460.3	71.7, 10831.8
	Mean (SD)	222.60 (153.305)	2776.19 (2712.922)	708.22 (1880.884)
	95% CI of Mean	187.32, 257.88	1896.75, 3655.62	81.09, 1335.34

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n (%)	10 (13.3)	4 (10.3)	2 (5.4)
	Geometric Mean (CV%)	547.75 (117.858)	1726.89 (231.079)	739.87 (122.947)
	95% CI of Geometric Mean	441.91, 678.95	1111.58, 2682.78	537.27, 1018.86
	Median	543.77	3120.59	639.03
	Q25, Q75	280.25, 1117.20	474.62, 4707.30	388.33, 1486.21
	Min, Max	67.7, 3042.3	80.8, 8518.3	112.5, 10831.8
	Mean (SD)	816.64 (742.153)	3052.91 (2268.559)	1238.86 (1830.911)
	95% CI of Mean	645.88, 987.40	2317.52, 3788.30	628.40, 1849.32

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n (%)	12 (16.0)	5 (12.8)	4 (10.8)
	Geometric Mean (CV%)	504.65 (116.136)	1571.01 (252.304)	813.65 (165.518)
	95% CI of Geometric Mean	407.99, 624.20	993.66, 2483.80	554.80, 1193.28
	Median	502.58	2612.20	826.73
	Q25, Q75	285.51, 1029.18	516.46, 4108.69	290.50, 1785.25
	Min, Max	75.7, 5635.4	45.3, 9121.1	87.0, 10831.8
	Mean (SD)	769.99 (844.406)	2905.53 (2452.489)	1482.39 (1925.237)
	95% CI of Mean	575.70, 964.27	2110.52, 3700.54	840.48, 2124.30

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.2 Descriptive Statistics of MHBMA in 24-hour Urine Collection - FAS****Parameter (units): MHBMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n (%)	15 (20.0)	1 (2.6)	3 (8.1)
	Geometric Mean (CV%)	504.26 (115.927)	1810.31 (170.156)	858.86 (130.542)
	95% CI of Geometric Mean	407.78, 623.57	1240.47, 2641.91	615.88, 1197.70
	Median	523.41	2928.90	699.05
	Q25, Q75	281.30, 1019.25	764.95, 4126.04	422.48, 1785.25
	Min, Max	75.0, 4843.7	139.1, 8355.8	69.4, 10831.8
	Mean (SD)	754.44 (767.305)	2879.15 (2186.120)	1413.72 (1865.548)
	95% CI of Mean	577.89, 930.98	2170.49, 3587.82	791.71, 2035.73

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		30		21	
	Missing, n (%)	10 (13.3)		5 (14.3)		3 (12.5)	
	BLOQ, n (%)	1 (1.5)		4 (13.3)		1 (4.8)	
	Geometric Mean (CV%)	1416.94 (109.332)		922.66 (170.171)		1145.57 (134.630)	
	95% CI of Geometric Mean	1137.42, 1765.14		596.93, 1426.12		721.09, 1819.91	
	Median	1434.51		1459.42		1634.33	
	Q25, Q75	991.54, 2764.71		396.83, 2127.66		579.88, 2450.70	
	Min, Max	155.7, 10792.9		96.3, 5519.7		125.0, 5922.7	
	Mean (SD)	2001.13 (1760.863)		1517.33 (1304.149)		1683.88 (1347.452)	
	95% CI of Mean	1564.81, 2437.46		1030.35, 2004.31		1070.52, 2297.23	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	4 (5.6)		2 (6.1)		3 (13.6)	
	Geometric Mean (CV%)	385.21 (78.638)		877.17 (176.153)		339.98 (95.178)	
	95% CI of Geometric Mean	326.87, 453.97		575.59, 1336.76		238.13, 485.40	
	Median	369.49	-75.37	1525.50	-10.94	418.21	-74.52
	Q25, Q75	255.12, 634.03	-80.42, -63.48	365.14, 2261.90	-29.84, 16.61	201.48, 564.24	-76.59, -63.21
	Min, Max	104.6, 4505.1	-89.9, 8.3	75.0, 3297.0	-51.2, 178.8	57.1, 1368.4	-88.4, 29.4
	Mean (SD)	506.04 (554.844)	-67.76 (22.079)	1430.16 (1064.878)	6.82 (59.654)	446.36 (328.007)	-66.45 (24.602)
	95% CI of Mean	374.70, 637.37	-73.24, -62.29	1052.57, 1807.76	-15.46, 29.10	300.92, 591.79	-77.65, -55.24

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	30 (42.3)		7 (21.2)		10 (45.5)	
	Geometric Mean (CV%)	120.03 (70.380)		629.39 (292.537)		111.83 (70.471)	
	95% CI of Geometric Mean	103.29, 139.48		369.44, 1072.24		84.38, 148.19	
	Median	136.25	-92.16	1120.85	-20.08	99.59	-93.10
	Q25, Q75	79.74, 172.75	-94.02, -88.93	230.91, 1824.00	-39.43, 4.32	62.66, 247.37	-94.53, -82.80
	Min, Max	29.1, 460.5	-98.8, 58.0	23.6, 4601.5	-88.9, 302.0	46.3, 310.9	-97.6, -16.2
	Mean (SD)	144.19 (86.811)	-86.27 (20.852)	1250.70 (1109.114)	-9.08 (71.967)	135.92 (88.194)	-84.09 (19.397)
	95% CI of Mean	123.64, 164.74	-91.44, -81.10	857.42, 1643.98	-35.96, 17.80	96.81, 175.02	-92.92, -75.25

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	33 (46.5)		5 (15.2)		12 (54.5)	
	Geometric Mean (CV%)	107.39 (57.153)		855.56 (268.299)		90.01 (58.160)	
	95% CI of Geometric Mean	94.69, 121.80		511.54, 1430.93		70.85, 114.36	
	Median	104.17	-92.66	1651.82	-12.04	87.50	-94.87
	Q25, Q75	73.17, 152.46	-95.13, -89.19	244.44, 2437.57	-28.82, 18.68	51.12, 137.72	-96.47, -86.30
	Min, Max	33.3, 396.2	-98.8, -19.9	56.1, 5332.6	-86.9, 270.1	45.5, 253.2	-98.2, 19.8
	Mean (SD)	123.67 (70.479)	-89.67 (11.142)	1686.24 (1464.089)	8.07 (67.346)	103.67 (58.503)	-81.87 (30.268)
	95% CI of Mean	106.99, 140.36	-92.43, -86.90	1167.09, 2205.38	-17.08, 33.22	77.73, 129.62	-95.66, -68.09

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	30 (42.3)		3 (9.1)		8 (36.4)	
	Geometric Mean (CV%)	130.57 (88.338)		745.66 (260.880)		137.12 (73.671)	
	95% CI of Geometric Mean	109.08, 156.28		448.53, 1239.63		102.40, 183.61	
	Median	136.60	-91.40	1385.07	-9.93	136.41	-91.45
	Q25, Q75	74.63, 223.44	-94.36, -82.44	179.86, 2602.92	-41.88, 25.25	91.49, 192.31	-94.38, -83.78
	Min, Max	23.0, 1168.4	-99.2, 57.0	49.5, 4308.3	-79.0, 256.8	42.4, 465.7	-96.9, 53.8
	Mean (SD)	173.38 (157.127)	-83.65 (23.588)	1469.85 (1281.378)	2.07 (68.094)	168.33 (115.562)	-73.16 (43.762)
	95% CI of Mean	136.19, 210.58	-89.50, -77.80	1015.49, 1924.22	-23.36, 27.51	117.09, 219.57	-93.09, -53.24

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	48 (67.6)		6 (18.2)		13 (59.1)	
	Geometric Mean (CV%)	113.01 (60.404)		760.36 (261.147)		93.99 (52.409)	
	95% CI of Geometric Mean	99.03, 128.96		457.27, 1264.34		75.54, 116.94	
	Median	116.55	-92.50	1401.87	-16.84	94.32	-94.93
	Q25, Q75	79.19, 168.78	-94.51, -87.31	182.28, 2495.18	-43.16, 17.27	58.41, 144.08	-95.65, -84.76
	Min, Max	23.6, 686.5	-98.8, -10.1	43.5, 4975.4	-67.6, 334.7	45.0, 200.0	-98.2, 46.0
	Mean (SD)	132.53 (90.045)	-87.52 (14.545)	1518.14 (1383.793)	2.27 (77.542)	105.29 (50.905)	-82.14 (32.744)
	95% CI of Mean	111.21, 153.84	-91.13, -83.91	1027.46, 2008.82	-26.69, 31.23	82.72, 127.87	-97.05, -67.23

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=32)		mCC (N=34)		SA (N=8)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		29		8	
	Missing, n (%)	4 (12.5)		5 (14.7)		0	
	Geometric Mean (CV%)	1318.03 (126.356)		981.48 (164.419)		1161.84 (192.301)	
	95% CI of Geometric Mean	902.45, 1924.98		635.12, 1516.71		410.70, 3286.68	
	Median	1190.33		1527.03		1468.70	
	Q25, Q75	715.74, 2970.07		437.28, 2127.66		668.68, 2598.49	
	Min, Max	155.7, 5934.6		96.3, 5519.7		125.0, 5922.7	
	Mean (SD)	1965.86 (1691.387)		1568.55 (1299.569)		1939.94 (1857.135)	
	95% CI of Mean	1310.00, 2621.72		1074.21, 2062.88		387.33, 3492.55	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=32)		mCC (N=34)		SA (N=8)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	28	32	29	8	8
	Missing, n (%)	1 (3.1)	4 (12.5)	2 (5.9)	5 (14.7)	0	0
	BLOQ, n (%)	5 (16.1)		3 (9.4)		2 (25.0)	
	Geometric Mean (CV%)	301.46 (122.007)		1017.53 (239.489)		296.01 (111.670)	
	95% CI of Geometric Mean	212.38, 427.89		618.43, 1674.17		139.51, 628.05	
	Median	274.65	-75.11	2073.52	19.39	328.76	-83.56
	Q25, Q75	166.45, 826.09	-88.09, -60.49	276.92, 2642.23	-8.07, 70.74	193.63, 581.77	-86.46, -26.18
	Min, Max	53.9, 2041.6	-98.5, 14.2	31.4, 4646.6	-82.3, 172.7	53.2, 888.3	-95.5, 116.1
	Mean (SD)	458.87 (439.737)	-64.62 (32.047)	1797.17 (1299.702)	26.74 (62.723)	393.72 (278.239)	-46.48 (74.645)
	95% CI of Mean	297.57, 620.17	-77.05, -52.19	1328.57, 2265.76	2.88, 50.61	161.10, 626.34	-108.89, 15.93

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=36)		mCC (N=34)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	33		30		7	
	Missing, n (%)	3 (8.3)		4 (11.8)		0	
	Geometric Mean (CV%)	1368.16 (131.537)		977.50 (159.425)		718.82 (170.184)	
	95% CI of Geometric Mean	958.97, 1951.95		642.32, 1487.59		244.46, 2113.65	
	Median	1234.13		1459.42		1025.41	
	Q25, Q75	688.37, 3070.45		437.28, 2127.66		308.19, 2460.57	
	Min, Max	155.7, 10792.9		96.3, 5519.7		125.0, 2736.4	
	Mean (SD)	2154.98 (2228.127)		1545.23 (1283.339)		1166.10 (1057.644)	
	95% CI of Mean	1364.91, 2945.04		1066.01, 2024.44		187.94, 2144.27	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=36)		mCC (N=34)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	36	33	32	30	7	7
	Missing, n (%)	0	3 (8.3)	2 (5.9)	4 (11.8)	0	0
	BLOQ, n (%)	7 (19.4)		4 (12.5)		3 (42.9)	
	Geometric Mean (CV%)	238.57 (95.292)		843.02 (228.401)		138.08 (78.720)	
	95% CI of Geometric Mean	181.76, 313.14		517.82, 1372.45		72.64, 262.47	
	Median	245.03	-84.59	1248.52	-12.26	140.19	-66.59
	Q25, Q75	129.07, 445.81	-93.50, -69.72	362.92, 2249.67	-41.92, 64.88	74.63, 316.20	-95.61, -40.30
	Min, Max	41.3, 1133.8	-98.0, 28.9	28.2, 5838.9	-59.6, 208.8	52.4, 342.6	-96.0, 1.4
	Mean (SD)	321.59 (257.642)	-71.91 (32.264)	1517.69 (1344.932)	12.13 (69.468)	169.01 (114.912)	-63.66 (36.179)
	95% CI of Mean	234.41, 408.77	-83.35, -60.46	1032.79, 2002.60	-13.81, 38.08	62.73, 275.29	-97.13, -30.20

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=41)		mCC (N=31)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		29		7	
	Missing, n (%)	4 (9.8)		2 (6.5)		0	
	Geometric Mean (CV%)	1335.44 (123.035)		948.90 (161.404)		718.82 (170.184)	
	95% CI of Geometric Mean	969.62, 1839.28		616.80, 1459.81		244.46, 2113.65	
	Median	1234.13		1391.81		1025.41	
	Q25, Q75	743.10, 2764.71		437.28, 2042.01		308.19, 2460.57	
	Min, Max	155.7, 10792.9		96.3, 5519.7		125.0, 2736.4	
	Mean (SD)	2040.73 (2101.972)		1518.77 (1297.703)		1166.10 (1057.644)	
	95% CI of Mean	1339.89, 2741.57		1025.15, 2012.40		187.94, 2144.27	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population****Parameter (units): MHBMA (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=41)		mCC (N=31)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	41	37	31	29	7	7
	Missing, n (%)	0	4 (9.8)	0	2 (6.5)	0	0
	BLOQ, n (%)	7 (17.1)		0		2 (28.6)	
	Geometric Mean (CV%)	259.12 (93.744)		1009.21 (178.348)		190.79 (75.800)	
	95% CI of Geometric Mean	201.67, 332.94		650.80, 1564.98		102.31, 355.78	
	Median	261.18	-84.28	1521.43	-1.63	206.73	-80.45
	Q25, Q75	130.28, 445.69	-89.55, -65.10	311.11, 2670.91	-28.72, 46.10	110.62, 373.64	-85.69, -11.50
	Min, Max	62.3, 1049.9	-97.8, 68.3	55.4, 6715.6	-50.9, 324.0	60.2, 391.6	-89.2, 19.8
	Mean (SD)	348.07 (272.882)	-71.66 (31.347)	1686.00 (1486.740)	36.09 (97.847)	225.79 (125.821)	-58.93 (44.139)
	95% CI of Mean	261.93, 434.21	-82.11, -61.20	1140.65, 2231.35	-1.13, 73.32	109.42, 342.16	-99.76, -18.11

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	67	30	21
	Missing, n (%)	8 (10.7)	5 (14.3)	3 (12.5)
	BLOQ, n (%)	1 (1.5)	4 (13.3)	1 (4.8)
	Geometric Mean (CV%)	2341.67 (103.877)	1462.77 (188.069)	1836.88 (137.729)
	95% CI of Geometric Mean	1900.63, 2885.06	924.16, 2315.27	1148.67, 2937.42
	Median	2248.02	2312.85	2470.32
	Q25, Q75	1314.14, 4607.88	711.99, 3314.45	1256.36, 4182.96
	Min, Max	262.5, 18776.1	144.8, 6973.1	201.7, 6392.2
	Mean (SD)	3254.56 (2853.550)	2442.70 (1951.606)	2666.63 (1888.323)
	95% CI of Mean	2558.52, 3950.60	1713.96, 3171.45	1807.07, 3526.19

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	4 (5.6)	2 (6.1)	3 (13.6)
	Geometric Mean (CV%)	622.76 (75.205)	1412.82 (196.811)	549.15 (91.491)
	95% CI of Geometric Mean	531.49, 729.70	904.24, 2207.43	388.62, 775.99
	Median	631.80	2473.04	570.32
	Q25, Q75	446.59, 1035.50	486.86, 3435.52	403.61, 1070.61
	Min, Max	131.0, 2762.5	103.0, 8175.0	103.8, 1529.2
	Mean (SD)	762.82 (488.439)	2428.23 (1999.594)	697.91 (436.559)
	95% CI of Mean	647.20, 878.43	1719.20, 3137.26	504.34, 891.47

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	30 (42.3)	7 (21.2)	10 (45.5)
	Geometric Mean (CV%)	197.08 (66.150)	1028.85 (302.291)	180.56 (57.652)
	95% CI of Geometric Mean	170.88, 227.29	599.76, 1764.91	142.38, 228.98
	Median	218.96	1829.77	169.34
	Q25, Q75	124.15, 291.55	264.88, 3336.08	117.80, 312.82
	Min, Max	52.9, 815.4	30.2, 8939.3	78.8, 432.5
	Mean (SD)	233.29 (137.428)	2138.51 (2087.706)	206.34 (106.994)
	95% CI of Mean	200.76, 265.83	1398.24, 2878.79	158.90, 253.78

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	33 (46.5)	5 (15.2)	12 (54.5)
	Geometric Mean (CV%)	175.69 (55.611)	1383.64 (278.186)	138.99 (49.275)
	95% CI of Geometric Mean	155.37, 198.66	820.90, 2332.14	113.03, 170.92
	Median	180.34	2651.04	128.04
	Q25, Q75	116.80, 244.40	324.29, 4216.85	99.75, 181.23
	Min, Max	66.4, 684.6	77.5, 8809.5	75.2, 369.6
	Mean (SD)	201.56 (115.975)	2718.53 (2267.736)	155.45 (82.671)
	95% CI of Mean	174.10, 229.01	1914.42, 3522.64	118.79, 192.11

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	30 (42.3)	3 (9.1)	8 (36.4)
	Geometric Mean (CV%)	215.34 (80.934)	1189.03 (253.201)	214.99 (63.645)
	95% CI of Geometric Mean	182.03, 254.74	719.86, 1963.98	166.00, 278.43
	Median	220.73	2314.65	211.75
	Q25, Q75	121.15, 376.90	255.36, 3833.44	143.90, 362.95
	Min, Max	40.6, 1983.5	95.2, 8379.3	77.8, 539.7
	Mean (SD)	279.39 (259.059)	2343.04 (2098.623)	251.10 (139.933)
	95% CI of Mean	218.07, 340.71	1598.90, 3087.19	189.05, 313.14

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	48 (67.6)	6 (18.2)	13 (59.1)
	Geometric Mean (CV%)	191.72 (54.744)	1246.41 (255.260)	156.74 (50.378)
	95% CI of Geometric Mean	169.83, 216.42	753.27, 2062.36	126.93, 193.53
	Median	192.50	2380.40	135.70
	Q25, Q75	137.40, 271.07	380.48, 3415.18	106.65, 227.81
	Min, Max	50.3, 1276.9	78.2, 10140.4	71.7, 466.0
	Mean (SD)	221.13 (155.787)	2469.48 (2338.716)	176.01 (95.544)
	95% CI of Mean	184.26, 258.01	1640.20, 3298.75	133.64, 218.38

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=32)	mCC (N=34)	SA (N=8)
		Value	Value	Value
Baseline	n	29	29	8
	Missing, n (%)	3 (9.4)	5 (14.7)	0
	Geometric Mean (CV%)	2101.96 (108.400)	1609.24 (170.857)	1784.88 (176.660)
	95% CI of Geometric Mean	1503.15, 2939.32	1031.69, 2510.09	660.00, 4826.91
	Median	2080.89	2314.07	2746.34
	Q25, Q75	1213.26, 4607.88	823.61, 3314.45	1221.60, 3576.84
	Min, Max	385.3, 7985.8	153.1, 6973.1	201.7, 6392.2
	Mean (SD)	2968.64 (2429.366)	2545.15 (1923.624)	2710.43 (1971.211)
	95% CI of Mean	2044.55, 3892.73	1813.44, 3276.87	1062.45, 4358.41

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=32)	mCC (N=34)	SA (N=8)
		Value	Value	Value
Day 30	n	31	32	8
	Missing, n (%)	1 (3.1)	2 (5.9)	0
	BLOQ, n (%)	5 (16.1)	3 (9.4)	2 (25.0)
	Geometric Mean (CV%)	475.28 (133.805)	1699.49 (234.538)	450.79 (80.778)
	95% CI of Geometric Mean	327.77, 689.17	1037.74, 2783.24	249.25, 815.27
	Median	441.56	3441.32	432.76
	Q25, Q75	250.66, 1117.20	469.28, 4656.05	345.70, 813.36
	Min, Max	67.7, 2880.8	80.8, 6850.5	112.5, 1044.1
	Mean (SD)	756.20 (748.117)	2994.08 (2135.134)	542.54 (314.880)
	95% CI of Mean	481.79, 1030.62	2224.28, 3763.89	279.28, 805.79

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=36)	mCC (N=34)	SA (N=7)
		Value	Value	Value
Baseline	n	34	30	7
	Missing, n (%)	2 (5.6)	4 (11.8)	0
	Geometric Mean (CV%)	2282.41 (116.346)	1592.24 (165.879)	1159.66 (180.085)
	95% CI of Geometric Mean	1652.71, 3152.02	1036.42, 2446.13	381.46, 3525.33
	Median	2109.07	2312.85	2034.45
	Q25, Q75	1245.80, 5364.24	823.61, 3314.45	408.76, 3397.20
	Min, Max	385.3, 18776.1	153.1, 6973.1	201.7, 3756.5
	Mean (SD)	3443.80 (3587.934)	2499.32 (1906.764)	1874.68 (1517.281)
	95% CI of Mean	2191.90, 4695.69	1787.32, 3211.32	471.43, 3277.94

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=36)	mCC (N=34)	SA (N=7)
		Value	Value	Value
Day 60	n	36	32	7
	Missing, n (%)	0	2 (5.9)	0
	BLOQ, n (%)	7 (19.4)	4 (12.5)	3 (42.9)
	Geometric Mean (CV%)	379.93 (91.887)	1419.70 (255.654)	228.18 (89.414)
	95% CI of Geometric Mean	291.56, 495.07	850.49, 2369.85	112.30, 463.59
	Median	400.61	2434.91	217.20
	Q25, Q75	225.49, 559.26	470.30, 3491.87	110.25, 464.27
	Min, Max	75.7, 2855.1	45.3, 9121.1	87.0, 760.7
	Mean (SD)	518.73 (513.279)	2670.25 (2366.834)	295.39 (240.216)
	95% CI of Mean	345.05, 692.40	1816.91, 3523.59	73.22, 517.56

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=41)	mCC (N=31)	SA (N=7)
		Value	Value	Value
Baseline	n	39	29	7
	Missing, n (%)	2 (4.9)	2 (6.5)	0
	Geometric Mean (CV%)	2156.33 (110.030)	1552.49 (168.987)	1159.66 (180.085)
	95% CI of Geometric Mean	1615.57, 2878.10	997.97, 2415.12	381.46, 3525.33
	Median	2080.89	2311.64	2034.45
	Q25, Q75	1245.80, 4017.92	823.61, 3204.37	408.76, 3397.20
	Min, Max	385.3, 18776.1	153.1, 6973.1	201.7, 3756.5
	Mean (SD)	3174.57 (3323.920)	2471.21 (1934.179)	1874.68 (1517.281)
	95% CI of Mean	2097.08, 4252.07	1735.49, 3206.94	471.43, 3277.94

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.2.3 Descriptive Statistics of MHBMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): MHBMA (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=41)	mCC (N=31)	SA (N=7)
		Value	Value	Value
Day 90	n	41	31	7
	BLOQ, n (%)	7 (17.1)	0	2 (28.6)
	Geometric Mean (CV%)	426.60 (98.500)	1690.04 (170.734)	315.50 (79.174)
	95% CI of Geometric Mean	328.95, 553.23	1101.01, 2594.19	165.50, 601.45
	Median	452.35	2443.07	407.65
	Q25, Q75	266.30, 720.26	489.66, 4126.04	302.55, 422.48
	Min, Max	78.9, 1737.2	139.1, 8355.8	69.4, 583.8
	Mean (SD)	578.34 (452.917)	2755.89 (2237.634)	365.29 (156.798)
	95% CI of Mean	435.38, 721.31	1935.12, 3576.67	220.27, 510.31

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		30		21	
	Missing, n (%)	8 (10.7)		5 (14.3)		3 (12.5)	
	Geometric Mean (CV%)	721.15 (47.744)		777.25 (48.195)		711.68 (58.646)	
	95% CI of Geometric Mean	645.68, 805.44		655.30, 921.88		555.64, 911.52	
	Median	724.29		812.51		791.98	
	Q25, Q75	566.62, 1016.99		587.16, 1038.11		583.02, 915.49	
	Min, Max	181.0, 2004.9		286.3, 1838.1		166.9, 1942.1	
	Mean (SD)	791.99 (337.256)		859.27 (402.023)		807.39 (407.169)	
	95% CI of Mean	709.72, 874.26		709.15, 1009.39		622.04, 992.73	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	282.07 (44.660)		673.53 (57.809)		234.26 (39.202)	
	95% CI of Geometric Mean	255.35, 311.59		558.45, 812.31		198.10, 277.02	
	Median	274.22	-63.16	701.25	-14.57	247.51	-69.21
	Q25, Q75	213.99, 375.00	-69.57, -53.35	497.87, 934.52	-24.08, 5.43	184.44, 303.89	-75.22, -63.99
	Min, Max	101.9, 1459.4	-80.4, 13.5	185.3, 1838.1	-54.3, 30.5	78.1, 443.0	-84.2, -2.9
	Mean (SD)	311.24 (173.630)	-57.96 (18.693)	772.16 (419.824)	-11.74 (24.140)	249.31 (85.673)	-63.39 (22.278)
	95% CI of Mean	270.73, 351.76	-62.52, -53.39	625.67, 918.64	-20.76, -2.72	211.32, 287.30	-73.54, -53.25

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	263.31 (35.893)		647.86 (53.114)		180.00 (53.654)	
	95% CI of Geometric Mean	242.77, 285.60		544.42, 770.95		144.01, 224.97	
	Median	268.67	-62.61	652.13	-14.01	173.69	-74.55
	Q25, Q75	209.56, 336.89	-70.44, -50.98	451.26, 821.62	-23.78, 0.00	130.33, 266.49	-79.49, -68.81
	Min, Max	134.7, 548.3	-81.9, 24.3	242.0, 1838.1	-58.8, 76.5	44.6, 378.8	-86.6, -57.6
	Mean (SD)	279.29 (96.706)	-60.56 (15.761)	733.16 (395.035)	-10.72 (27.604)	200.80 (91.381)	-73.09 (8.390)
	95% CI of Mean	256.72, 301.85	-64.41, -56.71	595.32, 871.00	-21.03, -0.41	160.28, 241.32	-76.91, -69.26

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	286.75 (36.169)		723.58 (52.443)		168.33 (41.220)	
	95% CI of Geometric Mean	264.22, 311.20		609.24, 859.38		141.21, 200.66	
	Median	280.42	-61.28	646.89	-9.94	170.64	-76.80
	Q25, Q75	243.94, 351.32	-70.13, -48.78	577.55, 932.52	-20.74, 11.83	135.27, 214.99	-82.28, -73.81
	Min, Max	106.5, 615.7	-84.7, 47.9	257.8, 2098.6	-49.5, 53.9	48.9, 303.8	-88.6, -9.0
	Mean (SD)	304.37 (107.378)	-57.33 (19.366)	816.95 (439.777)	-4.29 (24.819)	179.66 (60.644)	-73.15 (18.930)
	95% CI of Mean	279.31, 329.43	-62.06, -52.60	663.50, 970.40	-13.57, 4.98	152.77, 206.55	-81.78, -64.53

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	0		0		1 (4.5)	
	Geometric Mean (CV%)	276.90 (44.690)		683.45 (52.292)		169.91 (62.362)	
	95% CI of Geometric Mean	250.65, 305.89		575.71, 811.35		131.78, 219.08	
	Median	279.53	-59.97	692.56	-7.52	171.92	-78.30
	Q25, Q75	210.53, 367.00	-69.83, -50.07	513.27, 946.62	-25.61, 6.25	141.06, 235.88	-83.79, -68.63
	Min, Max	88.3, 755.6	-80.6, -7.9	213.0, 1838.1	-72.0, 80.4	28.4, 494.0	-93.2, -30.1
	Mean (SD)	302.44 (130.952)	-57.37 (16.824)	766.92 (386.602)	-7.79 (26.631)	194.41 (100.880)	-72.85 (15.881)
	95% CI of Mean	271.88, 333.00	-61.47, -53.26	632.02, 901.81	-17.74, 2.16	149.67, 239.14	-80.08, -65.61

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	283.88 (39.406)		655.19 (66.434)		151.43 (42.172)	
	95% CI of Geometric Mean	259.80, 310.20		530.57, 809.08		126.56, 181.19	
	Median	263.11	-62.46	686.62	-9.20	152.55	-79.94
	Q25, Q75	226.42, 369.11	-70.04, -53.04	539.17, 942.12	-36.67, 0.00	126.10, 182.10	-83.23, -70.12
	Min, Max	95.1, 730.2	-80.1, -7.3	105.6, 1838.1	-64.6, 110.5	56.7, 295.2	-93.0, -40.6
	Mean (SD)	305.28 (124.810)	-58.76 (15.735)	762.09 (397.101)	-12.91 (32.845)	163.13 (63.722)	-75.51 (14.122)
	95% CI of Mean	276.16, 334.41	-62.60, -54.91	623.53, 900.65	-25.18, -0.64	134.87, 191.38	-81.94, -69.07

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		29		12	
	Missing, n (%)	3 (7.5)		5 (14.7)		1 (7.7)	
	Geometric Mean (CV%)	737.59 (50.603)		725.68 (49.220)		697.33 (53.275)	
	95% CI of Geometric Mean	629.03, 864.88		607.85, 866.34		507.58, 957.99	
	Median	808.51		727.60		728.70	
	Q25, Q75	531.12, 1057.32		549.30, 929.79		480.84, 916.82	
	Min, Max	253.9, 2004.9		286.3, 1807.3		315.1, 1942.1	
	Mean (SD)	819.89 (378.250)		804.02 (375.707)		784.67 (431.072)	
	95% CI of Mean	693.77, 946.01		661.10, 946.94		510.78, 1058.57	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	37	33	29	13	12
	Missing, n (%)	0	3 (7.5)	1 (2.9)	5 (14.7)	0	1 (7.7)
	Geometric Mean (CV%)	369.55 (39.090)		691.59 (54.099)		228.14 (62.087)	
	95% CI of Geometric Mean	327.56, 416.92		577.86, 827.70		161.56, 322.16	
	Median	364.98	-48.00	637.25	-7.91	232.67	-63.30
	Q25, Q75	300.89, 463.60	-59.17, -26.60	444.88, 964.82	-21.30, 20.03	198.10, 333.33	-78.34, -49.18
	Min, Max	101.2, 809.3	-87.5, 0.4	343.6, 2288.3	-56.7, 149.2	84.5, 497.2	-86.1, -37.1
	Mean (SD)	394.44 (143.150)	-44.76 (22.465)	789.67 (451.453)	0.46 (38.612)	262.65 (140.031)	-63.88 (16.600)
	95% CI of Mean	348.66, 440.23	-52.26, -37.27	629.59, 949.75	-14.23, 15.15	178.02, 347.27	-74.43, -53.32

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	35		30		11	
	Missing, n (%)	4 (10.3)		5 (14.3)		1 (8.3)	
	Geometric Mean (CV%)	715.71 (48.262)		731.46 (48.511)		584.30 (60.739)	
	95% CI of Geometric Mean	611.60, 837.54		616.07, 868.45		400.99, 851.41	
	Median	720.21		768.05		661.94	
	Q25, Q75	531.12, 1016.99		549.30, 929.79		375.00, 915.49	
	Min, Max	276.5, 2004.9		286.3, 1807.3		166.9, 988.7	
	Mean (SD)	790.76 (365.868)		807.91 (369.787)		656.52 (277.835)	
	95% CI of Mean	665.07, 916.44		669.83, 946.00		469.86, 843.17	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	35	34	30	11	11
	Missing, n (%)	0	4 (10.3)	1 (2.9)	5 (14.3)	1 (8.3)	1 (8.3)
	Geometric Mean (CV%)	289.18 (59.522)		580.28 (64.250)		219.07 (68.779)	
	95% CI of Geometric Mean	241.90, 345.71		472.67, 712.40		144.21, 332.80	
	Median	287.91	-55.50	659.06	-19.50	244.44	-62.10
	Q25, Q75	182.48, 453.90	-70.86, -39.99	428.57, 833.33	-38.07, 7.61	132.56, 344.29	-70.09, -43.27
	Min, Max	86.6, 724.1	-84.7, 48.7	146.6, 1933.2	-53.5, 105.7	67.2, 572.7	-84.6, 1.9
	Mean (SD)	331.77 (168.496)	-52.08 (27.579)	677.18 (378.283)	-13.08 (35.023)	256.62 (143.042)	-57.26 (24.159)
	95% CI of Mean	277.14, 386.39	-61.55, -42.60	545.18, 809.17	-26.17, 0.00	160.52, 352.73	-73.50, -41.03

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	43		29		9	
	Missing, n (%)	4 (8.5)		3 (9.4)		0	
	Geometric Mean (CV%)	739.73 (47.524)		727.91 (49.374)		543.55 (64.749)	
	95% CI of Geometric Mean	643.81, 849.94		609.42, 869.44		344.91, 856.58	
	Median	741.26		727.60		644.97	
	Q25, Q75	535.89, 1057.32		549.30, 929.79		375.00, 897.48	
	Min, Max	276.5, 2004.9		286.3, 1807.3		166.9, 918.1	
	Mean (SD)	814.60 (363.228)		806.73 (376.274)		619.00 (284.794)	
	95% CI of Mean	702.81, 926.39		663.59, 949.86		400.08, 837.92	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	43	32	29	9	9
	Missing, n (%)	0	4 (8.5)	0	3 (9.4)	0	
	BLOQ, n (%)	0		0		1 (11.1)	
	Geometric Mean (CV%)	314.05 (38.577)		606.10 (81.767)		177.90 (107.152)	
	95% CI of Geometric Mean	281.51, 350.34		468.27, 784.48		90.83, 348.41	
	Median	314.85	-56.30	655.35	-8.55	251.33	-65.78
	Q25, Q75	233.66, 401.37	-65.78, -41.90	444.59, 946.90	-32.32, 14.07	174.04, 313.32	-71.65, -44.77
	Min, Max	115.6, 744.4	-89.4, -1.6	73.4, 1652.8	-81.3, 168.9	22.1, 383.1	-94.1, 8.3
	Mean (SD)	336.09 (128.590)	-53.82 (18.413)	741.66 (432.302)	-5.54 (48.286)	222.46 (113.491)	-57.21 (31.129)
	95% CI of Mean	298.33, 373.85	-59.50, -48.15	585.79, 897.52	-23.91, 12.84	135.22, 309.70	-81.14, -33.28

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	70	31	22
	Missing, n (%)	5 (6.7)	4 (11.4)	2 (8.3)
	Geometric Mean (CV%)	1206.40 (46.598)	1254.72 (47.842)	1138.82 (54.422)
	95% CI of Geometric Mean	1085.39, 1340.90	1062.24, 1482.07	908.61, 1427.35
	Median	1297.67	1207.25	1163.57
	Q25, Q75	852.10, 1650.43	976.13, 1670.49	957.28, 1687.61
	Min, Max	435.7, 2839.9	325.3, 3007.6	249.2, 2096.0
	Mean (SD)	1325.02 (574.575)	1377.95 (609.263)	1262.73 (518.069)
	95% CI of Mean	1188.02, 1462.03	1154.47, 1601.44	1033.03, 1492.43

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	466.68 (45.321)	1109.30 (63.411)	378.45 (38.332)
	95% CI of Geometric Mean	422.21, 515.84	908.48, 1354.50	322.45, 444.17
	Median	454.44	1097.54	380.02
	Q25, Q75	357.01, 682.54	848.36, 1479.35	292.58, 492.37
	Min, Max	171.3, 963.3	219.9, 2941.5	172.7, 688.8
	Mean (SD)	508.62 (202.987)	1278.39 (652.879)	403.31 (144.826)
	95% CI of Mean	461.58, 555.65	1054.12, 1502.67	340.68, 465.95

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	439.68 (37.855)	1079.16 (52.031)	306.48 (47.395)
	95% CI of Geometric Mean	403.94, 478.59	912.14, 1276.76	252.26, 372.35
	Median	428.78	992.46	306.54
	Q25, Q75	344.52, 557.82	814.64, 1479.35	264.02, 395.86
	Min, Max	167.4, 949.5	323.9, 2580.1	79.8, 615.7
	Mean (SD)	469.29 (171.904)	1208.40 (587.889)	333.80 (132.917)
	95% CI of Mean	429.46, 509.12	1006.45, 1410.35	276.32, 391.29

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	475.72 (40.676)	1193.33 (51.135)	261.31 (44.173)
	95% CI of Geometric Mean	434.48, 520.87	1011.25, 1408.20	217.69, 313.65
	Median	478.41	1282.91	291.81
	Q25, Q75	367.49, 630.94	849.30, 1542.24	210.01, 339.25
	Min, Max	152.5, 1056.7	255.4, 2766.4	62.3, 462.4
	Mean (SD)	511.28 (192.641)	1321.66 (584.914)	279.93 (90.899)
	95% CI of Mean	466.65, 555.92	1120.73, 1522.59	240.62, 319.24

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n (%)	0	0	1 (4.3)
	Geometric Mean (CV%)	463.40 (44.461)	1106.70 (55.812)	273.97 (61.375)
	95% CI of Geometric Mean	419.97, 511.32	925.42, 1323.48	214.54, 349.86
	Median	470.57	1159.94	311.69
	Q25, Q75	366.32, 595.64	811.18, 1479.35	223.03, 407.15
	Min, Max	136.1, 1282.8	235.7, 2735.2	34.0, 507.0
	Mean (SD)	504.37 (208.379)	1247.95 (606.151)	305.73 (118.268)
	95% CI of Mean	456.08, 552.65	1039.72, 1456.17	254.58, 356.88

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	489.28 (42.325)	1090.19 (68.647)	258.25 (55.336)
	95% CI of Geometric Mean	445.36, 537.53	880.64, 1349.59	206.52, 322.93
	Median	496.71	1129.72	325.90
	Q25, Q75	379.35, 645.78	830.49, 1520.40	191.40, 353.92
	Min, Max	137.5, 1358.1	127.3, 2973.4	79.5, 533.0
	Mean (SD)	529.04 (211.912)	1271.28 (668.077)	288.05 (120.572)
	95% CI of Mean	479.94, 578.14	1041.79, 1500.78	235.91, 340.20

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	38	30	12
	Missing, n (%)	2 (5.0)	4 (11.8)	1 (7.7)
	Geometric Mean (CV%)	1212.41 (48.201)	1213.68 (51.561)	1092.45 (50.149)
	95% CI of Geometric Mean	1043.28, 1408.95	1012.42, 1454.93	808.54, 1476.04
	Median	1297.67	1185.74	1101.81
	Q25, Q75	837.08, 1651.30	972.51, 1670.49	658.10, 1542.49
	Min, Max	510.1, 2839.9	325.3, 3007.6	605.1, 2261.0
	Mean (SD)	1339.32 (605.326)	1351.21 (637.587)	1210.04 (572.406)
	95% CI of Mean	1140.35, 1538.29	1113.13, 1589.29	846.35, 1573.73

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Day 30	n	40	34	13
	Geometric Mean (CV%)	598.75 (47.649)	1176.30 (57.065)	374.73 (46.213)
	95% CI of Geometric Mean	518.10, 691.96	977.37, 1415.71	287.25, 488.87
	Median	632.49	1077.30	429.00
	Q25, Q75	488.78, 804.63	815.86, 1647.36	289.71, 458.98
	Min, Max	99.8, 1370.2	400.1, 3460.4	145.5, 768.6
	Mean (SD)	650.81 (246.317)	1354.10 (780.002)	407.36 (167.262)
	95% CI of Mean	572.03, 729.59	1081.94, 1626.26	306.28, 508.44

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	37	31	12
	Missing, n (%)	2 (5.1)	4 (11.4)	0
	Geometric Mean (CV%)	1182.64 (49.184)	1214.52 (50.593)	957.32 (63.432)
	95% CI of Geometric Mean	1012.63, 1381.18	1019.42, 1446.95	661.59, 1385.22
	Median	1204.78	1186.77	1045.76
	Q25, Q75	837.08, 1651.30	972.51, 1670.49	654.42, 1383.77
	Min, Max	510.1, 2839.9	325.3, 3007.6	249.2, 2261.0
	Mean (SD)	1312.84 (615.658)	1347.62 (627.188)	1094.34 (544.604)
	95% CI of Mean	1107.56, 1518.11	1117.56, 1577.68	748.31, 1440.37

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Day 60	n	39	35	12
	Geometric Mean (CV%)	469.74 (57.773)	979.84 (66.048)	370.35 (42.233)
	95% CI of Geometric Mean	394.73, 559.00	796.88, 1204.81	286.29, 479.08
	Median	518.24	1043.71	405.77
	Q25, Q75	345.45, 721.14	696.71, 1313.14	278.91, 479.95
	Min, Max	121.2, 1201.1	161.2, 3671.6	156.9, 648.0
	Mean (SD)	529.96 (239.079)	1151.91 (691.186)	396.64 (142.825)
	95% CI of Mean	452.45, 607.46	914.47, 1389.35	305.88, 487.39

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	45	29	9
	Missing, n (%)	2 (4.3)	3 (9.4)	0
	Geometric Mean (CV%)	1204.87 (47.427)	1190.92 (51.096)	881.58 (71.696)
	95% CI of Geometric Mean	1052.37, 1379.47	991.55, 1430.37	537.36, 1446.30
	Median	1257.16	1184.71	958.23
	Q25, Q75	852.10, 1651.30	972.51, 1500.65	625.21, 1370.15
	Min, Max	510.1, 2839.9	325.3, 3007.6	249.2, 2261.0
	Mean (SD)	1327.18 (587.719)	1324.51 (629.863)	1039.22 (599.418)
	95% CI of Mean	1150.60, 1503.75	1084.91, 1564.10	578.46, 1499.98

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Day 90	n	47	32	9
	BLOQ, n (%)	0	0	1 (11.1)
	Geometric Mean (CV%)	526.94 (35.222)	1006.31 (82.998)	304.53 (84.470)
	95% CI of Geometric Mean	476.60, 582.60	775.14, 1306.43	173.23, 535.32
	Median	553.89	1093.44	336.00
	Q25, Q75	410.60, 670.76	679.91, 1631.69	214.64, 496.98
	Min, Max	228.7, 1063.4	87.9, 3131.6	60.5, 699.7
	Mean (SD)	556.53 (182.313)	1232.28 (727.957)	367.20 (201.625)
	95% CI of Mean	503.00, 610.07	969.82, 1494.74	212.21, 522.18

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.1 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Baseline	n	41	26	16	14	12	9
	Missing, n (%)	5 (10.9)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Geometric Mean (CV%)	654.53 (50.156)	840.25 (39.263)	678.39 (44.300)	907.99 (48.387)	583.79 (57.408)	926.80 (48.339)
	95% CI of Geometric Mean	563.63, 760.09	721.08, 979.11	541.39, 850.05	696.74, 1183.29	415.89, 819.47	651.64, 1318.14
	Median	693.94	860.40	621.40	888.08	691.36	904.76
	Q25, Q75	556.14, 917.84	583.92, 1087.23	482.35, 873.15	727.60, 1207.79	445.56, 878.55	752.03, 1010.80
	Min, Max	181.0, 1519.9	501.4, 2004.9	381.5, 1807.3	286.3, 1838.1	166.9, 988.7	419.3, 1942.1
	Mean (SD)	722.30 (304.854)	901.88 (362.015)	743.43 (366.895)	991.66 (412.107)	649.57 (263.358)	1017.81 (481.590)
	95% CI of Mean	626.07, 818.53	755.66, 1048.11	547.93, 938.94	753.71, 1229.60	482.24, 816.91	647.62, 1388.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.1 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 1	n	44	29	19	15	13	9
	Missing, n (%)	2 (4.3)	0	1 (5.0)	0	2 (13.3)	0
	Geometric Mean (CV%)	261.26 (38.600)	316.86 (50.992)	617.70 (54.113)	751.54 (62.125)	195.19 (36.241)	304.89 (24.422)
	95% CI of Geometric Mean	233.27, 292.61	263.90, 380.44	483.83, 788.61	547.71, 1031.23	157.85, 241.36	253.39, 366.86
	Median	262.91	278.23	567.29	774.23	185.87	303.89
	Q25, Q75	213.48, 346.75	220.47, 411.10	415.33, 908.98	539.81, 957.43	180.30, 233.91	265.96, 335.07
	Min, Max	101.9, 499.1	132.5, 1459.4	288.5, 1620.4	185.3, 1838.1	78.1, 338.7	195.5, 443.0
	Mean (SD)	278.03 (93.044)	361.64 (244.667)	700.61 (381.788)	862.78 (460.758)	205.42 (63.816)	312.71 (74.194)
	95% CI of Mean	249.73, 306.32	268.57, 454.72	516.59, 884.63	607.62, 1117.94	166.85, 243.98	255.68, 369.75

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.1 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 1	n	41	26	16	14	12	9
	Missing, n (%)	5 (10.9)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-62.27	-65.10	-12.07	-14.81	-70.80	-66.56
	Q25, Q75	-68.03, -53.35	-74.35, -55.22	-25.79, 15.37	-24.08, 0.00	-76.39, -64.79	-74.00, -63.40
	Min, Max	-80.4, 13.5	-77.3, 0.0	-51.8, 30.5	-54.3, 21.1	-79.9, -2.9	-84.2, -4.4
	Mean (SD)	-56.71 (18.715)	-59.92 (18.856)	-8.50 (27.630)	-15.45 (19.783)	-64.00 (22.332)	-62.59 (23.532)
	95% CI of Mean	-62.63, -50.80	-67.54, -52.30	-23.23, 6.23	-26.88, -4.02	-78.19, -49.80	-80.68, -44.50

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.1 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 2	n	44	29	19	15	13	9
	Missing, n (%)	2 (4.3)	0	1 (5.0)	0	2 (13.3)	0
	Geometric Mean (CV%)	248.27 (35.045)	287.90 (35.711)	569.57 (48.736)	762.65 (54.581)	150.20 (49.360)	233.78 (47.944)
	95% CI of Geometric Mean	223.86, 275.34	252.35, 328.46	455.95, 711.51	574.79, 1011.91	113.26, 199.17	164.80, 331.64
	Median	246.65	287.29	638.50	696.64	144.44	260.40
	Q25, Q75	195.69, 321.45	243.21, 350.84	394.40, 735.29	554.55, 1008.45	130.33, 181.85	191.42, 328.53
	Min, Max	134.7, 505.6	135.6, 548.3	242.0, 1470.2	307.3, 1838.1	44.6, 277.8	115.1, 378.8
	Mean (SD)	262.85 (92.161)	304.22 (99.681)	630.44 (306.252)	863.27 (463.460)	163.92 (66.012)	254.06 (99.913)
	95% CI of Mean	234.83, 290.88	266.30, 342.14	482.83, 778.06	606.61, 1119.93	124.03, 203.82	177.26, 330.87

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.1 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 2	n	41	26	16	14	12	9
	Missing, n (%)	5 (10.9)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-61.94	-63.64	-13.10	-14.01	-73.95	-74.55
	Q25, Q75	-70.44, -50.53	-68.74, -57.12	-30.69, 5.68	-23.40, -3.45	-78.52, -68.85	-81.07, -63.39
	Min, Max	-80.5, 24.3	-81.9, -43.2	-58.8, 76.5	-50.3, 11.0	-82.1, -57.6	-86.6, -58.6
	Mean (SD)	-59.02 (18.188)	-63.00 (10.791)	-6.61 (33.952)	-15.42 (18.031)	-73.13 (7.176)	-73.03 (10.255)
	95% CI of Mean	-64.76, -53.27	-67.36, -58.64	-24.71, 11.49	-25.84, -5.00	-77.70, -68.57	-80.92, -65.14

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.1 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 3	n	44	29	19	15	13	9
	Missing, n (%)	2 (4.3)	0	1 (5.0)	0	2 (13.3)	0
	Geometric Mean (CV%)	269.28 (37.123)	315.46 (32.808)	652.44 (47.481)	824.93 (56.655)	169.58 (27.686)	166.54 (59.254)
	95% CI of Geometric Mean	241.41, 300.36	279.33, 356.26	525.00, 810.83	615.91, 1104.87	143.89, 199.85	109.24, 253.90
	Median	278.60	320.00	614.38	822.83	164.81	188.93
	Q25, Q75	229.82, 349.72	248.80, 353.29	564.54, 765.54	597.73, 1077.69	137.43, 212.20	131.36, 236.98
	Min, Max	106.5, 594.3	177.6, 615.7	296.2, 1785.7	257.8, 2098.6	108.2, 267.6	48.9, 303.8
	Mean (SD)	286.16 (100.646)	331.99 (113.055)	722.52 (369.848)	936.55 (502.578)	175.58 (49.424)	185.56 (76.966)
	95% CI of Mean	255.56, 316.77	288.98, 375.00	544.26, 900.79	658.22, 1214.87	145.71, 205.45	126.39, 244.72

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.1 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 3	n	41	26	16	14	12	9
	Missing, n (%)	5 (10.9)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-59.20	-63.89	-2.67	-10.96	-76.07	-82.28
	Q25, Q75	-70.39, -44.90	-68.94, -53.47	-20.42, 16.58	-20.74, 3.73	-79.73, -67.50	-87.00, -75.66
	Min, Max	-84.7, 47.9	-79.9, -33.9	-49.5, 53.9	-43.3, 40.7	-85.3, -9.0	-88.6, -72.5
	Mean (SD)	-54.72 (22.952)	-61.45 (10.883)	-1.26 (27.297)	-7.76 (22.138)	-67.25 (23.078)	-81.03 (6.431)
	95% CI of Mean	-61.97, -47.47	-65.85, -57.05	-15.82, 13.29	-20.54, 5.03	-81.91, -52.58	-85.98, -76.08

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.1 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 4	n	44	29	19	15	13	9
	Missing, n (%)	2 (4.3)	0	1 (5.0)	0	2 (13.3)	0
	BLOQ, n (%)	0	0	0	0	0	1 (11.1)
	Geometric Mean (CV%)	267.51 (39.837)	291.78 (51.752)	654.80 (40.207)	721.55 (67.072)	160.99 (33.385)	183.68 (99.915)
	95% CI of Geometric Mean	238.04, 300.62	242.42, 351.18	543.34, 789.11	514.85, 1011.23	132.27, 195.94	96.89, 348.20
	Median	271.89	315.03	664.67	722.50	163.75	205.96
	Q25, Q75	203.32, 331.52	217.80, 391.22	467.35, 912.16	566.08, 1031.43	141.06, 186.14	162.73, 268.46
	Min, Max	119.3, 755.6	88.3, 665.2	365.1, 1595.5	213.0, 1838.1	82.7, 291.5	28.4, 494.0
	Mean (SD)	288.36 (122.294)	323.81 (142.630)	705.06 (298.098)	845.28 (475.685)	168.93 (55.109)	231.20 (139.934)
	95% CI of Mean	251.17, 325.54	269.55, 378.06	561.37, 848.74	581.85, 1108.71	135.63, 202.24	123.63, 338.76

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.1 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 4	n	41	26	16	14	12	9
	Missing, n (%)	5 (10.9)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-57.91	-61.78	-3.42	-15.03	-76.28	-83.79
	Q25, Q75	-69.69, -48.39	-71.65, -53.89	-16.95, 5.31	-28.88, 6.25	-79.73, -69.29	-83.93, -68.63
	Min, Max	-77.2, -7.9	-80.6, -33.3	-37.8, 80.4	-72.0, 21.7	-85.8, -30.1	-93.2, -46.0
	Mean (SD)	-54.65 (18.836)	-61.65 (12.179)	-2.79 (27.598)	-13.49 (25.248)	-70.43 (16.277)	-76.06 (15.678)
	95% CI of Mean	-60.60, -48.70	-66.58, -56.73	-17.51, 11.92	-28.08, 1.09	-80.78, -60.08	-88.12, -64.01

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.1 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 5	n	44	29	19	15	13	9
	Missing, n (%)	2 (4.3)	0	1 (5.0)	0	2 (13.3)	0
	Geometric Mean (CV%)	266.20 (39.906)	312.98 (36.934)	618.08 (64.563)	705.42 (70.479)	149.54 (23.206)	154.20 (64.776)
	95% CI of Geometric Mean	236.83, 299.21	273.17, 358.59	465.03, 821.49	496.26, 1002.72	130.20, 171.74	97.83, 243.06
	Median	254.96	301.44	609.88	811.23	146.22	160.38
	Q25, Q75	217.05, 323.28	239.43, 381.82	398.06, 942.12	558.33, 1062.18	135.93, 174.19	126.10, 282.89
	Min, Max	95.1, 730.2	156.3, 688.1	162.2, 1669.9	105.6, 1838.1	99.2, 231.2	56.7, 295.2
	Mean (SD)	286.15 (115.587)	334.31 (134.501)	720.58 (398.889)	814.67 (402.271)	153.20 (35.357)	177.46 (91.609)
	95% CI of Mean	251.00, 321.30	283.14, 385.48	528.32, 912.85	591.89, 1037.44	131.83, 174.57	107.04, 247.89

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.1 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 5	n	41	26	16	14	12	9
	Missing, n (%)	5 (10.9)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-60.20	-62.83	-6.94	-22.86	-77.02	-80.26
	Q25, Q75	-68.71, -49.84	-70.46, -54.60	-28.98, 6.75	-38.52, 0.00	-83.16, -66.67	-91.43, -72.01
	Min, Max	-78.4, -7.3	-80.1, -44.1	-64.6, 110.5	-63.1, 15.3	-84.6, -40.6	-93.0, -67.8
	Mean (SD)	-55.96 (18.119)	-63.16 (9.766)	-5.67 (38.293)	-21.18 (24.007)	-71.65 (15.827)	-80.65 (10.101)
	95% CI of Mean	-61.69, -50.24	-67.11, -59.21	-26.08, 14.74	-35.05, -7.32	-81.71, -61.59	-88.42, -72.88

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.1 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=28)	Females (N=19)	Males (N=19)	Females (N=13)	Males (N=7)	Females (N=2)
Baseline	n	26	17	17	12	7	2
	Missing, n (%)	2 (7.1)	2 (10.5)	2 (10.5)	1 (7.7)	0	0
	Geometric Mean (CV%)	678.55 (49.160)	844.14 (42.452)	646.26 (48.086)	861.54 (47.037)	469.65 (65.251)	906.44 (1.406)
	95% CI of Geometric Mean	562.29, 818.83	684.72, 1040.66	511.16, 817.05	648.50, 1144.57	270.74, 814.70	798.91, 1028.45
	Median	709.11	912.28	608.19	888.08	542.42	906.48
	Q25, Q75	486.86, 937.50	539.45, 1087.23	458.16, 816.50	717.44, 1122.95	315.12, 795.45	897.48, 915.49
	Min, Max	276.5, 1519.9	501.4, 2004.9	297.3, 1807.3	286.3, 1577.7	166.9, 918.1	897.5, 915.5
	Mean (SD)	749.30 (332.094)	914.46 (395.577)	717.19 (371.356)	933.56 (360.365)	536.86 (269.622)	906.48 (12.740)
	95% CI of Mean	615.16, 883.44	711.07, 1117.86	526.25, 908.13	704.59, 1162.53	287.50, 786.23	792.02, 1020.95

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.1 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=28)	Females (N=19)	Males (N=19)	Females (N=13)	Males (N=7)	Females (N=2)
Day 90	n	28	19	19	13	7	2
	BLOQ, n (%)	0	0	0	0	1 (14.3)	0
	Geometric Mean (CV%)	287.47 (33.885)	357.75 (41.854)	566.19 (81.375)	669.53 (84.853)	155.91 (123.308)	282.33 (14.805)
	95% CI of Geometric Mean	252.97, 326.68	294.76, 434.19	401.56, 798.32	429.04, 1044.82	64.07, 379.37	75.19, 1060.03
	Median	290.64	362.01	564.79	655.79	180.72	283.87
	Q25, Q75	232.75, 363.47	259.67, 511.40	334.57, 982.30	629.71, 911.49	105.08, 318.08	254.42, 313.32
	Min, Max	115.6, 488.1	180.8, 744.4	129.9, 1652.8	73.4, 1642.2	22.1, 383.1	254.4, 313.3
	Mean (SD)	302.29 (95.794)	385.89 (155.231)	707.61 (470.577)	791.42 (382.235)	204.92 (123.566)	283.87 (41.648)
	95% CI of Mean	265.14, 339.44	311.07, 460.72	480.79, 934.42	560.43, 1022.41	90.63, 319.20	-90.33, 658.06

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.1 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=28)	Females (N=19)	Males (N=19)	Females (N=13)	Males (N=7)	Females (N=2)
%Change from baseline to Day 90	n	26	17	17	12	7	2
	Missing, n (%)	2 (7.1)	2 (10.5)	2 (10.5)	1 (7.7)	0	0
	Median	-54.92	-56.61	-8.55	-11.88	-65.36	-68.71
	Q25, Q75	-66.59, -41.90	-64.89, -46.47	-32.32, 24.51	-36.35, 6.72	-83.71, -29.38	-71.65, -65.78
	Min, Max	-82.2, -18.6	-89.4, -1.6	-81.3, 168.9	-74.3, 58.5	-94.1, 8.3	-71.7, -65.8
	Mean (SD)	-54.03 (16.822)	-53.51 (21.159)	0.71 (55.985)	-14.39 (35.071)	-53.92 (35.106)	-68.71 (4.155)
	95% CI of Mean	-60.83, -47.23	-64.39, -42.62	-28.08, 29.50	-36.68, 7.90	-86.40, -21.45	-106.05, -31.38

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.2 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Baseline	n	39	28	17	13	11	10
	Missing, n (%)	4 (9.3)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Geometric Mean (CV%)	636.80 (46.606)	857.58 (43.297)	720.67 (45.356)	857.99 (51.672)	604.52 (62.897)	851.60 (49.378)
	95% CI of Geometric Mean	551.54, 735.23	730.24, 1007.12	576.97, 900.16	639.45, 1151.20	410.17, 890.97	609.70, 1189.48
	Median	663.20	937.50	634.77	868.04	791.98	815.33
	Q25, Q75	566.62, 881.36	582.62, 1153.02	549.30, 920.73	727.60, 1147.29	375.00, 915.49	644.97, 1010.80
	Min, Max	181.0, 1322.0	370.6, 2004.9	381.5, 1807.3	286.3, 1838.1	166.9, 988.7	419.3, 1942.1
	Mean (SD)	692.86 (264.034)	930.06 (382.043)	791.78 (386.245)	947.53 (420.454)	682.59 (287.373)	944.67 (486.499)
	95% CI of Mean	607.27, 778.46	781.91, 1078.20	593.19, 990.37	693.44, 1201.61	489.53, 875.66	596.64, 1292.69

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.2 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Day 1	n	42	31	20	14	12	10
	Missing, n (%)	1 (2.3)	1 (3.1)	0	1 (6.7)	1 (7.7)	1 (9.1)
	Geometric Mean (CV%)	248.74 (39.647)	334.47 (45.055)	609.64 (51.229)	776.59 (65.193)	215.26 (42.086)	259.28 (34.632)
	95% CI of Geometric Mean	220.81, 280.19	285.67, 391.60	486.34, 764.18	550.75, 1095.02	166.54, 278.23	203.80, 329.86
	Median	249.47	366.15	560.91	800.24	216.96	263.53
	Q25, Q75	211.71, 330.69	227.12, 404.32	445.24, 803.64	567.29, 1195.04	185.16, 287.74	180.49, 306.52
	Min, Max	101.9, 499.1	182.8, 1459.4	288.5, 1805.6	185.3, 1838.1	78.1, 338.7	165.5, 443.0
	Mean (SD)	266.03 (95.555)	372.50 (230.511)	685.72 (377.012)	895.64 (460.167)	229.61 (76.911)	272.95 (93.583)
	95% CI of Mean	236.25, 295.81	287.95, 457.06	509.27, 862.17	629.94, 1161.34	180.74, 278.48	206.00, 339.90

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.2 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
%Change from baseline to Day 1	n	39	28	17	13	11	10
	Missing, n (%)	4 (9.3)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-62.06	-64.40	-14.96	-14.49	-69.21	-71.37
	Q25, Q75	-69.05, -52.01	-70.51, -54.52	-24.08, 14.90	-19.06, 0.11	-74.75, -63.40	-77.56, -65.59
	Min, Max	-80.4, 13.5	-75.3, 0.0	-51.8, 30.5	-54.3, 28.5	-79.9, -2.9	-84.2, -4.4
	Mean (SD)	-57.53 (18.753)	-58.56 (18.936)	-12.21 (24.837)	-11.13 (24.189)	-61.81 (22.535)	-65.13 (23.070)
	95% CI of Mean	-63.61, -51.44	-65.90, -51.21	-24.98, 0.57	-25.76, 3.49	-76.96, -46.67	-81.64, -48.63

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.2 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Day 2	n	42	31	20	14	12	10
	Missing, n (%)	1 (2.3)	1 (3.1)	0	1 (6.7)	1 (7.7)	1 (9.1)
	Geometric Mean (CV%)	244.17 (34.585)	291.67 (35.332)	624.20 (52.666)	683.21 (55.424)	167.05 (63.623)	196.86 (41.450)
	95% CI of Geometric Mean	219.88, 271.13	257.19, 330.78	495.17, 786.86	506.72, 921.17	115.33, 241.95	148.06, 261.75
	Median	243.24	286.80	662.59	641.83	149.54	199.20
	Q25, Q75	186.77, 312.20	243.14, 387.33	444.11, 816.40	451.26, 1008.45	129.19, 258.68	132.31, 277.78
	Min, Max	135.6, 505.3	134.7, 548.3	242.0, 1654.6	307.3, 1838.1	44.6, 378.8	115.1, 328.5
	Mean (SD)	258.00 (88.009)	308.12 (101.813)	700.06 (356.948)	780.44 (453.679)	192.31 (102.379)	210.98 (80.392)
	95% CI of Mean	230.57, 285.43	270.77, 345.47	533.00, 867.12	518.49, 1042.39	127.26, 257.37	153.46, 268.49

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.2 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
%Change from baseline to Day 2	n	39	28	17	13	11	10
	Missing, n (%)	4 (9.3)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-61.57	-65.21	-10.76	-19.75	-73.28	-78.07
	Q25, Q75	-68.74, -48.90	-73.56, -58.42	-21.86, -2.51	-31.33, 0.00	-76.68, -59.77	-81.07, -68.89
	Min, Max	-80.5, 24.3	-81.9, -41.7	-58.8, 76.5	-50.3, 48.5	-82.1, -57.6	-86.6, -63.4
	Mean (SD)	-57.77 (18.062)	-64.46 (11.000)	-7.71 (28.674)	-14.66 (26.747)	-70.53 (8.867)	-75.91 (7.227)
	95% CI of Mean	-63.63, -51.91	-68.73, -60.19	-22.45, 7.04	-30.83, 1.50	-76.49, -64.56	-81.08, -70.73

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.2 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Day 3	n	42	31	20	14	12	10
	Missing, n (%)	1 (2.3)	1 (3.1)	0	1 (6.7)	1 (7.7)	1 (9.1)
	Geometric Mean (CV%)	270.79 (34.711)	309.90 (37.071)	673.54 (48.085)	801.58 (58.414)	190.28 (24.485)	145.31 (53.408)
	95% CI of Geometric Mean	243.77, 300.80	271.67, 353.50	544.08, 833.81	586.24, 1096.01	163.23, 221.81	101.54, 207.95
	Median	280.25	309.76	640.55	687.68	197.61	147.13
	Q25, Q75	226.89, 340.43	243.94, 437.35	571.04, 865.58	597.73, 1200.00	158.39, 225.99	117.29, 188.93
	Min, Max	106.5, 594.3	141.3, 615.7	296.2, 2098.6	257.8, 1838.1	129.4, 267.6	48.9, 303.8
	Mean (SD)	285.67 (94.855)	329.70 (119.259)	748.81 (402.812)	914.28 (486.269)	195.34 (46.127)	160.85 (72.526)
	95% CI of Mean	256.10, 315.23	285.95, 373.45	560.29, 937.34	633.51, 1195.05	166.03, 224.65	108.96, 212.74

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.2 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
%Change from baseline to Day 3	n	39	28	17	13	11	10
	Missing, n (%)	4 (9.3)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-58.38	-64.29	1.28	-12.65	-74.93	-83.32
	Q25, Q75	-67.84, -44.82	-71.49, -56.19	-17.22, 14.02	-31.67, 4.59	-78.30, -63.35	-87.00, -76.80
	Min, Max	-84.7, 47.9	-79.9, -25.2	-49.5, 53.9	-43.3, 38.0	-80.9, -9.0	-88.6, -72.5
	Mean (SD)	-53.77 (22.812)	-62.29 (11.854)	-0.32 (26.010)	-9.49 (23.128)	-64.96 (23.087)	-82.16 (5.646)
	95% CI of Mean	-61.17, -46.37	-66.89, -57.69	-13.70, 13.06	-23.47, 4.49	-80.48, -49.45	-86.21, -78.12

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.2 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Day 4	n	42	31	20	14	12	10
	Missing, n (%)	1 (2.3)	1 (3.1)	0	1 (6.7)	1 (7.7)	1 (9.1)
	BLOQ, n (%)	0	0	0	0	0	1 (10.0)
	Geometric Mean (CV%)	260.32 (46.461)	301.05 (41.277)	683.00 (44.061)	684.08 (65.205)	183.19 (50.256)	155.25 (77.945)
	95% CI of Geometric Mean	226.81, 298.77	260.29, 348.21	560.79, 831.84	485.12, 964.64	135.50, 247.66	94.83, 254.15
	Median	264.77	284.97	648.40	885.59	183.60	168.38
	Q25, Q75	194.08, 348.67	245.56, 378.63	525.59, 769.60	467.35, 968.32	131.96, 241.57	148.31, 205.96
	Min, Max	88.3, 755.6	119.3, 665.2	365.1, 1735.4	213.0, 1838.1	82.7, 494.0	28.4, 382.6
	Mean (SD)	286.15 (130.749)	324.51 (130.069)	749.88 (374.995)	791.26 (415.683)	204.27 (109.386)	182.57 (94.001)
	95% CI of Mean	245.40, 326.90	276.80, 372.22	574.37, 925.39	551.25, 1031.27	134.76, 273.77	115.32, 249.82

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.2 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
%Change from baseline to Day 4	n	39	28	17	13	11	10
	Missing, n (%)	4 (9.3)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-57.91	-64.73	-0.86	-17.49	-72.67	-81.85
	Q25, Q75	-67.38, -46.63	-72.41, -54.59	-11.72, 15.08	-31.36, -1.90	-79.56, -46.04	-83.93, -74.61
	Min, Max	-80.6, -12.7	-77.4, -7.9	-37.8, 80.4	-72.0, 15.0	-85.8, -30.1	-93.2, -57.4
	Mean (SD)	-54.25 (17.648)	-61.70 (14.837)	0.60 (26.936)	-18.76 (22.726)	-66.74 (18.004)	-79.56 (10.229)
	95% CI of Mean	-59.98, -48.53	-67.46, -55.94	-13.25, 14.45	-32.49, -5.02	-78.84, -54.64	-86.88, -72.24

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.2 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Day 5	n	42	31	20	14	12	10
	Missing, n (%)	1 (2.3)	1 (3.1)	0	1 (6.7)	1 (7.7)	1 (9.1)
	Geometric Mean (CV%)	269.41 (40.377)	304.74 (37.411)	632.17 (57.033)	689.53 (81.732)	160.43 (26.167)	141.29 (58.142)
	95% CI of Geometric Mean	238.68, 304.10	266.85, 348.01	493.14, 810.40	456.24, 1042.12	136.23, 188.93	96.04, 207.86
	Median	262.00	303.39	637.08	824.93	159.63	130.95
	Q25, Q75	217.12, 359.85	236.47, 396.37	489.65, 899.63	539.17, 1263.93	139.81, 180.37	114.17, 231.19
	Min, Max	95.1, 730.2	125.5, 688.1	162.2, 1669.9	105.6, 1838.1	99.2, 295.2	56.7, 287.7
	Mean (SD)	290.53 (122.867)	325.27 (126.635)	713.45 (348.093)	831.58 (462.984)	165.67 (47.430)	160.08 (81.891)
	95% CI of Mean	252.23, 328.82	278.82, 371.73	550.53, 876.37	564.26, 1098.91	135.52, 195.81	101.49, 218.66

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.2 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
%Change from baseline to Day 5	n	39	28	17	13	11	10
	Missing, n (%)	4 (9.3)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-59.47	-65.19	-7.60	-23.30	-78.67	-82.36
	Q25, Q75	-68.71, -52.33	-72.62, -54.93	-29.42, -0.85	-37.20, 0.00	-83.08, -63.21	-91.43, -72.01
	Min, Max	-78.4, -7.3	-80.1, -32.7	-64.6, 110.5	-63.1, 15.3	-84.6, -40.6	-93.0, -67.9
	Mean (SD)	-55.74 (17.105)	-62.96 (12.727)	-8.05 (37.597)	-19.27 (25.399)	-70.54 (16.146)	-80.97 (9.499)
	95% CI of Mean	-61.29, -50.19	-67.90, -58.02	-27.38, 11.29	-34.62, -3.92	-81.39, -59.69	-87.77, -74.17

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.2 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=26)	>19 cig/day (N=21)	10-19 cig/day (N=13)	>19 cig/day (N=19)	10-19 cig/day (N=3)	>19 cig/day (N=6)
Baseline	n	19	24	17	12	6	3
	Missing, n (%)	2 (9.5)	2 (7.7)	2 (10.5)	1 (7.7)	0	0
	Geometric Mean (CV%)	627.72 (44.959)	842.41 (45.464)	720.67 (45.356)	738.28 (57.173)	456.03 (74.142)	772.19 (16.835)
	95% CI of Geometric Mean	510.45, 771.94	701.50, 1011.61	576.97, 900.16	526.59, 1035.08	227.68, 913.37	509.75, 1169.74
	Median	693.94	942.73	634.77	851.66	458.71	795.45
	Q25, Q75	443.06, 865.30	547.79, 1153.02	549.30, 920.73	574.77, 1038.54	315.12, 915.49	644.97, 897.48
	Min, Max	276.5, 1322.0	370.6, 2004.9	381.5, 1807.3	286.3, 1577.7	166.9, 918.1	645.0, 897.5
	Mean (SD)	681.12 (271.068)	920.27 (396.296)	791.78 (386.245)	827.90 (377.571)	538.85 (316.530)	779.30 (127.026)
	95% CI of Mean	550.46, 811.77	752.92, 1087.61	593.19, 990.37	588.00, 1067.80	206.67, 871.03	463.75, 1094.85

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.2 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=26)	>19 cig/day (N=21)	10-19 cig/day (N=13)	>19 cig/day (N=19)	10-19 cig/day (N=3)	>19 cig/day (N=6)
Day 90	n	21	26	19	13	6	3
	BLOQ, n (%)	0	0	0	0	1 (16.7)	0
	Geometric Mean (CV%)	288.11 (28.624)	336.69 (44.541)	585.17 (59.516)	638.04 (117.053)	172.74 (143.422)	188.70 (54.141)
	95% CI of Geometric Mean	253.55, 327.37	283.53, 399.82	448.76, 763.05	363.95, 1118.52	56.96, 523.80	53.55, 664.92
	Median	293.16	325.65	649.11	835.10	247.02	251.33
	Q25, Q75	231.84, 360.78	259.67, 478.70	400.00, 742.62	570.74, 1157.72	174.04, 318.08	105.08, 254.42
	Min, Max	180.8, 475.0	115.6, 744.4	227.9, 1652.8	73.4, 1585.1	22.1, 383.1	105.1, 254.4
	Mean (SD)	299.19 (85.309)	365.88 (150.121)	675.93 (396.194)	837.71 (480.100)	231.89 (131.815)	203.61 (85.340)
	95% CI of Mean	260.36, 338.03	305.24, 426.52	484.97, 866.89	547.59, 1127.84	93.55, 370.23	-8.39, 415.61

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.1.2 Descriptive Statistics of 3-HPMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=26)	>19 cig/day (N=21)	10-19 cig/day (N=13)	>19 cig/day (N=19)	10-19 cig/day (N=3)	>19 cig/day (N=6)
%Change from baseline to Day 90	n	19	24	17	12	6	3
	Missing, n (%)	2 (9.5)	2 (7.7)	2 (10.5)	1 (7.7)	0	0
	Median	-51.33	-58.71	-8.55	-11.17	-55.06	-71.65
	Q25, Q75	-64.81, -40.49	-68.65, -44.94	-31.88, 10.14	-47.49, 31.34	-65.78, -29.38	-83.71, -68.40
	Min, Max	-74.2, -18.6	-89.4, -1.6	-54.6, 54.8	-81.3, 168.9	-94.1, 8.3	-83.7, -68.4
	Mean (SD)	-51.02 (15.923)	-56.04 (20.225)	-10.47 (28.317)	1.46 (68.391)	-48.52 (35.392)	-74.59 (8.063)
	95% CI of Mean	-58.70, -43.34	-64.59, -47.50	-25.04, 4.09	-42.00, 44.92	-85.67, -11.37	-94.62, -54.55

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		36		36	
	Missing, n (%)	9 (11.3)		5 (12.2)		3 (7.7)	
	Geometric Mean (CV%)	721.91 (48.101)		790.65 (49.146)		762.35 (56.935)	
	95% CI of Geometric Mean	648.01, 804.24		675.51, 925.41		637.22, 912.06	
	Median	724.29		838.77		802.02	
	Q25, Q75	566.62, 1016.99		597.67, 1042.59		562.72, 999.77	
	Min, Max	181.0, 2004.9		286.3, 1838.1		166.9, 1942.1	
	Mean (SD)	794.67 (345.379)		873.93 (391.950)		861.58 (412.636)	
	95% CI of Mean	712.92, 876.43		741.31, 1006.56		721.96, 1001.20	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	282.46 (43.788)		690.47 (54.626)		266.61 (66.925)	
	95% CI of Geometric Mean	256.84, 310.63		586.36, 813.06		217.65, 326.56	
	Median	274.22	-63.16	725.07	-14.57	265.96	-70.40
	Q25, Q75	213.99, 375.00	-69.57, -53.35	509.16, 945.97	-23.11, 2.77	180.49, 335.07	-77.38, -54.80
	Min, Max	101.9, 1459.4	-80.4, 13.5	185.3, 1838.1	-54.3, 59.1	78.1, 1433.6	-85.8, 0.0
	Mean (SD)	310.56 (169.773)	-57.95 (18.543)	780.78 (397.972)	-10.48 (25.263)	330.34 (280.691)	-57.77 (29.757)
	95% CI of Mean	272.02, 349.10	-62.34, -53.55	653.50, 908.07	-19.03, -1.93	236.75, 423.93	-67.84, -47.69

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	265.50 (35.386)		686.33 (52.053)		223.27 (83.389)	
	95% CI of Geometric Mean	245.59, 287.04		586.83, 802.68		175.23, 284.48	
	Median	270.09	-62.43	669.81	-9.91	216.54	-73.91
	Q25, Q75	213.57, 336.89	-70.44, -50.80	491.45, 922.13	-23.02, 2.48	133.72, 313.52	-80.28, -59.20
	Min, Max	134.7, 548.3	-81.9, 24.3	242.0, 1838.1	-58.8, 106.4	44.6, 1433.6	-93.6, 0.0
	Mean (SD)	281.12 (95.557)	-60.30 (15.653)	770.56 (386.150)	-6.24 (32.112)	298.59 (291.630)	-63.17 (27.689)
	95% CI of Mean	259.43, 302.82	-64.01, -56.59	647.06, 894.06	-17.11, 4.63	201.35, 395.83	-72.55, -53.80

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	287.10 (35.572)		747.79 (50.657)		206.88 (76.173)	
	95% CI of Geometric Mean	265.46, 310.50		641.79, 871.29		165.10, 259.22	
	Median	280.42	-61.28	694.98	-6.03	174.59	-76.18
	Q25, Q75	243.94, 351.32	-70.13, -48.42	578.05, 957.44	-17.53, 11.10	143.97, 236.98	-83.29, -66.61
	Min, Max	106.5, 615.7	-84.7, 47.9	257.8, 2098.6	-49.5, 53.9	48.9, 1433.6	-91.3, 0.0
	Mean (SD)	304.18 (105.559)	-57.34 (19.097)	836.05 (419.193)	-2.49 (24.690)	276.18 (293.027)	-64.13 (30.856)
	95% CI of Mean	280.21, 328.14	-61.87, -52.82	701.98, 970.12	-10.85, 5.87	178.48, 373.89	-74.58, -53.69

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	0		0		1 (2.7)	
	Geometric Mean (CV%)	279.89 (43.951)		704.47 (51.023)		226.59 (83.162)	
	95% CI of Geometric Mean	254.42, 307.90		604.01, 821.62		177.93, 288.55	
	Median	284.97	-59.97	725.03	-7.45	205.96	-74.34
	Q25, Q75	210.94, 367.00	-69.83, -48.78	525.59, 976.56	-22.83, 7.77	162.73, 291.45	-81.88, -51.70
	Min, Max	88.3, 755.6	-80.6, -7.9	213.0, 1838.1	-72.0, 80.4	28.4, 1433.6	-93.2, 0.0
	Mean (SD)	304.77 (128.962)	-56.98 (16.951)	784.84 (371.657)	-6.75 (25.256)	301.25 (291.564)	-61.92 (29.419)
	95% CI of Mean	275.50, 334.05	-61.00, -52.97	665.97, 903.70	-15.30, 1.80	204.03, 398.47	-71.88, -51.96

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	284.64 (38.405)		692.48 (63.214)		198.65 (80.090)	
	95% CI of Geometric Mean	261.65, 309.65		575.27, 833.57		157.09, 251.21	
	Median	265.09	-61.32	756.25	-7.19	162.29	-75.56
	Q25, Q75	227.60, 360.98	-70.04, -52.85	544.89, 1062.46	-35.19, 3.76	135.80, 239.13	-83.70, -65.48
	Min, Max	95.1, 730.2	-80.1, -7.3	105.6, 1838.1	-64.6, 138.6	56.7, 1433.6	-93.0, 0.0
	Mean (SD)	305.05 (121.738)	-58.62 (15.704)	794.09 (384.138)	-7.45 (39.795)	271.73 (296.939)	-65.31 (29.399)
	95% CI of Mean	277.41, 332.68	-62.34, -54.90	671.23, 916.95	-20.91, 6.02	172.72, 370.74	-75.27, -55.36

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	379.13 (41.609)		745.48 (54.057)		317.80 (66.783)	
	95% CI of Geometric Mean	346.25, 415.12		634.03, 876.52		259.54, 389.13	
	Median	367.10	-47.62	684.10	-5.33	286.41	-60.10
	Q25, Q75	300.90, 490.57	-59.17, -26.35	467.34, 1008.52	-20.96, 14.83	213.77, 474.10	-74.22, -40.87
	Min, Max	101.2, 1059.4	-87.5, 95.5	343.6, 2288.3	-56.7, 149.2	84.5, 1433.6	-88.0, 54.7
	Mean (SD)	408.87 (162.026)	-41.42 (27.904)	847.54 (458.054)	-0.61 (35.019)	384.63 (278.769)	-49.63 (32.551)
	95% CI of Mean	372.09, 445.65	-48.03, -34.81	701.04, 994.04	-12.47, 11.24	291.68, 477.58	-60.65, -38.62

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	319.59 (53.427)		647.44 (67.003)		297.47 (72.345)	
	95% CI of Geometric Mean	285.23, 358.10		532.86, 786.65		239.60, 369.31	
	Median	332.48	-54.87	708.65	-14.07	307.74	-63.76
	Q25, Q75	221.53, 483.21	-68.95, -37.61	462.79, 932.34	-36.60, 7.82	183.75, 388.79	-73.17, -25.30
	Min, Max	86.6, 786.7	-84.7, 48.7	146.6, 1933.2	-53.5, 105.7	67.2, 1433.6	-90.5, 1.9
	Mean (SD)	358.47 (165.482)	-48.97 (27.059)	761.60 (421.267)	-10.18 (33.222)	368.54 (282.046)	-51.93 (30.667)
	95% CI of Mean	320.90, 396.03	-55.38, -42.56	626.87, 896.34	-21.42, 1.07	274.50, 462.59	-62.31, -41.55

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	0		0		1 (2.7)	
	Geometric Mean (CV%)	318.59 (48.466)		680.39 (78.269)		302.85 (85.927)	
	95% CI of Geometric Mean	287.04, 353.60		545.43, 848.73		236.35, 388.07	
	Median	320.83	-55.73	732.21	-8.13	318.08	-59.39
	Q25, Q75	239.64, 402.00	-65.78, -40.49	540.61, 1086.56	-31.17, 14.97	217.65, 406.49	-76.09, -30.71
	Min, Max	92.5, 949.2	-89.5, 56.4	73.4, 1838.1	-81.3, 168.9	22.1, 1433.6	-94.1, 35.1
	Mean (SD)	352.83 (166.497)	-50.58 (25.224)	818.22 (441.369)	-4.55 (43.659)	383.53 (284.607)	-49.46 (34.055)
	95% CI of Mean	315.04, 390.63	-56.56, -44.61	677.06, 959.38	-19.32, 10.23	288.64, 478.43	-60.98, -37.93

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	74	37	37
	Missing, n (%)	6 (7.5)	4 (9.8)	2 (5.1)
	Geometric Mean (CV%)	1208.50 (45.761)	1282.07 (49.230)	1243.05 (56.298)
	95% CI of Geometric Mean	1092.37, 1336.97	1097.63, 1497.51	1043.54, 1480.70
	Median	1269.86	1240.28	1302.45
	Q25, Q75	869.43, 1650.43	1028.66, 1671.57	930.62, 1876.26
	Min, Max	435.7, 2839.9	325.3, 3007.6	249.2, 3196.3
	Mean (SD)	1323.67 (566.638)	1414.79 (632.474)	1404.36 (678.099)
	95% CI of Mean	1192.38, 1454.95	1203.91, 1625.67	1178.26, 1630.45

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 1	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	466.03 (44.458)	1131.87 (60.353)	441.87 (67.508)
	95% CI of Geometric Mean	423.47, 512.86	949.29, 1349.57	361.26, 540.48
	Median	455.38	1145.35	394.09
	Q25, Q75	357.01, 637.48	942.53, 1472.45	297.15, 594.80
	Min, Max	171.3, 963.3	219.9, 2941.5	172.7, 3196.3
	Mean (SD)	506.54 (199.520)	1291.93 (641.756)	565.30 (585.851)
	95% CI of Mean	461.55, 551.53	1089.36, 1494.49	372.73, 757.87

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 2	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	441.59 (36.889)	1136.92 (51.360)	377.63 (78.783)
	95% CI of Geometric Mean	407.42, 478.63	975.89, 1324.52	300.52, 474.53
	Median	439.23	1198.81	333.87
	Q25, Q75	349.10, 541.16	856.91, 1542.51	273.30, 433.70
	Min, Max	167.4, 949.5	323.9, 2691.8	79.8, 3196.3
	Mean (SD)	469.83 (167.594)	1268.71 (600.316)	513.67 (599.119)
	95% CI of Mean	432.03, 507.62	1079.22, 1458.20	316.74, 710.60

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 3	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	475.32 (39.682)	1223.06 (49.264)	328.13 (82.342)
	95% CI of Geometric Mean	436.05, 518.13	1055.71, 1416.92	259.02, 415.68
	Median	478.41	1305.68	292.58
	Q25, Q75	375.18, 627.94	948.60, 1542.24	221.05, 390.89
	Min, Max	152.5, 1056.7	255.4, 2766.4	62.3, 3196.3
	Mean (SD)	509.31 (188.404)	1346.86 (580.024)	466.62 (608.392)
	95% CI of Mean	466.83, 551.80	1163.78, 1529.94	266.65, 666.60

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 4	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n (%)	0	0	1 (2.6)
	Geometric Mean (CV%)	466.00 (43.520)	1144.52 (53.366)	366.28 (87.946)
	95% CI of Geometric Mean	424.23, 511.88	977.24, 1340.44	285.60, 469.75
	Median	478.48	1242.66	340.74
	Q25, Q75	370.23, 595.64	883.92, 1522.78	252.07, 501.39
	Min, Max	136.1, 1282.8	235.7, 2735.2	34.0, 3196.3
	Mean (SD)	505.48 (204.186)	1277.81 (584.803)	509.73 (601.033)
	95% CI of Mean	459.44, 551.53	1093.22, 1462.40	312.17, 707.29

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 5	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	489.62 (41.218)	1154.59 (65.033)	338.94 (87.998)
	95% CI of Geometric Mean	447.78, 535.36	957.22, 1392.64	264.25, 434.74
	Median	494.55	1223.90	347.81
	Q25, Q75	382.54, 622.44	910.08, 1554.19	232.10, 422.79
	Min, Max	137.5, 1358.1	127.3, 2973.4	79.5, 3196.3
	Mean (SD)	527.51 (206.899)	1325.40 (641.641)	484.70 (606.923)
	95% CI of Mean	480.86, 574.17	1122.87, 1527.93	285.21, 684.20

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	627.33 (47.409)	1200.15 (56.512)	520.06 (67.147)
	95% CI of Geometric Mean	566.77, 694.37	1016.41, 1417.11	425.56, 635.54
	Median	657.31	1190.99	501.51
	Q25, Q75	495.52, 806.47	823.07, 1647.36	366.41, 693.00
	Min, Max	99.8, 1683.3	400.1, 3460.4	145.5, 3196.3
	Mean (SD)	686.93 (288.190)	1375.79 (765.445)	646.53 (578.819)
	95% CI of Mean	621.95, 751.91	1134.18, 1617.40	456.27, 836.78

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	524.29 (54.101)	1060.40 (66.021)	501.40 (69.564)
	95% CI of Geometric Mean	467.69, 587.75	877.03, 1282.10	407.85, 616.41
	Median	534.12	1117.20	487.70
	Q25, Q75	401.81, 738.26	798.52, 1495.65	375.52, 648.05
	Min, Max	121.2, 1683.3	161.2, 3671.6	156.9, 3196.3
	Mean (SD)	589.28 (284.719)	1242.85 (708.952)	630.21 (579.355)
	95% CI of Mean	525.08, 653.47	1019.07, 1466.63	439.77, 820.64

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS****Parameter (units): 3-HPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n (%)	0	0	1 (2.6)
	Geometric Mean (CV%)	543.88 (48.763)	1081.59 (74.840)	492.31 (83.135)
	95% CI of Geometric Mean	490.09, 603.58	876.28, 1335.01	387.94, 624.76
	Median	560.49	1190.78	442.07
	Q25, Q75	414.69, 684.45	825.31, 1618.06	349.20, 739.38
	Min, Max	135.2, 1746.1	87.9, 3131.6	60.5, 3196.3
	Mean (SD)	604.40 (303.787)	1282.07 (678.153)	645.67 (600.092)
	95% CI of Mean	535.90, 672.90	1068.01, 1496.12	448.42, 842.92

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		30		21	
	Missing, n (%)	8 (10.7)		5 (14.3)		3 (12.5)	
	Geometric Mean (CV%)	721.15 (47.744)		777.25 (48.195)		711.68 (58.646)	
	95% CI of Geometric Mean	645.68, 805.44		655.30, 921.88		555.64, 911.52	
	Median	724.29		812.51		791.98	
	Q25, Q75	566.62, 1016.99		587.16, 1038.11		583.02, 915.49	
	Min, Max	181.0, 2004.9		286.3, 1838.1		166.9, 1942.1	
	Mean (SD)	791.99 (337.256)		859.27 (402.023)		807.39 (407.169)	
	95% CI of Mean	709.72, 874.26		709.15, 1009.39		622.04, 992.73	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	282.07 (44.660)		673.53 (57.809)		234.26 (39.202)	
	95% CI of Geometric Mean	255.35, 311.59		558.45, 812.31		198.10, 277.02	
	Median	274.22	-63.16	701.25	-14.57	247.51	-69.21
	Q25, Q75	213.99, 375.00	-69.57, -53.35	497.87, 934.52	-24.08, 5.43	184.44, 303.89	-75.22, -63.99
	Min, Max	101.9, 1459.4	-80.4, 13.5	185.3, 1838.1	-54.3, 30.5	78.1, 443.0	-84.2, -2.9
	Mean (SD)	311.24 (173.630)	-57.96 (18.693)	772.16 (419.824)	-11.74 (24.140)	249.31 (85.673)	-63.39 (22.278)
	95% CI of Mean	270.73, 351.76	-62.52, -53.39	625.67, 918.64	-20.76, -2.72	211.32, 287.30	-73.54, -53.25

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	263.31 (35.893)		647.86 (53.114)		180.00 (53.654)	
	95% CI of Geometric Mean	242.77, 285.60		544.42, 770.95		144.01, 224.97	
	Median	268.67	-62.61	652.13	-14.01	173.69	-74.55
	Q25, Q75	209.56, 336.89	-70.44, -50.98	451.26, 821.62	-23.78, 0.00	130.33, 266.49	-79.49, -68.81
	Min, Max	134.7, 548.3	-81.9, 24.3	242.0, 1838.1	-58.8, 76.5	44.6, 378.8	-86.6, -57.6
	Mean (SD)	279.29 (96.706)	-60.56 (15.761)	733.16 (395.035)	-10.72 (27.604)	200.80 (91.381)	-73.09 (8.390)
	95% CI of Mean	256.72, 301.85	-64.41, -56.71	595.32, 871.00	-21.03, -0.41	160.28, 241.32	-76.91, -69.26

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	286.75 (36.169)		723.58 (52.443)		168.33 (41.220)	
	95% CI of Geometric Mean	264.22, 311.20		609.24, 859.38		141.21, 200.66	
	Median	280.42	-61.28	646.89	-9.94	170.64	-76.80
	Q25, Q75	243.94, 351.32	-70.13, -48.78	577.55, 932.52	-20.74, 11.83	135.27, 214.99	-82.28, -73.81
	Min, Max	106.5, 615.7	-84.7, 47.9	257.8, 2098.6	-49.5, 53.9	48.9, 303.8	-88.6, -9.0
	Mean (SD)	304.37 (107.378)	-57.33 (19.366)	816.95 (439.777)	-4.29 (24.819)	179.66 (60.644)	-73.15 (18.930)
	95% CI of Mean	279.31, 329.43	-62.06, -52.60	663.50, 970.40	-13.57, 4.98	152.77, 206.55	-81.78, -64.53

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	0		0		1 (4.5)	
	Geometric Mean (CV%)	276.90 (44.690)		683.45 (52.292)		169.91 (62.362)	
	95% CI of Geometric Mean	250.65, 305.89		575.71, 811.35		131.78, 219.08	
	Median	279.53	-59.97	692.56	-7.52	171.92	-78.30
	Q25, Q75	210.53, 367.00	-69.83, -50.07	513.27, 946.62	-25.61, 6.25	141.06, 235.88	-83.79, -68.63
	Min, Max	88.3, 755.6	-80.6, -7.9	213.0, 1838.1	-72.0, 80.4	28.4, 494.0	-93.2, -30.1
	Mean (SD)	302.44 (130.952)	-57.37 (16.824)	766.92 (386.602)	-7.79 (26.631)	194.41 (100.880)	-72.85 (15.881)
	95% CI of Mean	271.88, 333.00	-61.47, -53.26	632.02, 901.81	-17.74, 2.16	149.67, 239.14	-80.08, -65.61

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	283.88 (39.406)		655.19 (66.434)		151.43 (42.172)	
	95% CI of Geometric Mean	259.80, 310.20		530.57, 809.08		126.56, 181.19	
	Median	263.11	-62.46	686.62	-9.20	152.55	-79.94
	Q25, Q75	226.42, 369.11	-70.04, -53.04	539.17, 942.12	-36.67, 0.00	126.10, 182.10	-83.23, -70.12
	Min, Max	95.1, 730.2	-80.1, -7.3	105.6, 1838.1	-64.6, 110.5	56.7, 295.2	-93.0, -40.6
	Mean (SD)	305.28 (124.810)	-58.76 (15.735)	762.09 (397.101)	-12.91 (32.845)	163.13 (63.722)	-75.51 (14.122)
	95% CI of Mean	276.16, 334.41	-62.60, -54.91	623.53, 900.65	-25.18, -0.64	134.87, 191.38	-81.94, -69.07

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=32)		mCC (N=34)		SA (N=8)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		29		8	
	Missing, n (%)	3 (9.4)		5 (14.7)		0	
	Geometric Mean (CV%)	753.10 (49.554)		725.68 (49.220)		700.14 (66.360)	
	95% CI of Geometric Mean	630.14, 900.05		607.85, 866.34		422.53, 1160.14	
	Median	864.95		727.60		846.47	
	Q25, Q75	531.12, 1016.99		549.30, 929.79		397.13, 916.82	
	Min, Max	298.2, 2004.9		286.3, 1807.3		315.1, 1942.1	
	Mean (SD)	834.85 (388.152)		804.02 (375.707)		822.25 (520.693)	
	95% CI of Mean	687.20, 982.50		661.10, 946.94		386.94, 1257.57	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=32)		mCC (N=34)		SA (N=8)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	32	29	33	29	8	8
	Missing, n (%)	0	3 (9.4)	1 (2.9)	5 (14.7)	0	0
	Geometric Mean (CV%)	378.46 (39.287)		691.59 (54.099)		252.87 (72.807)	
	95% CI of Geometric Mean	330.13, 433.85		577.86, 827.70		146.59, 436.21	
	Median	368.96	-48.00	637.25	-7.91	266.42	-58.00
	Q25, Q75	311.48, 463.60	-59.17, -26.60	444.88, 964.82	-21.30, 20.03	168.20, 468.21	-77.40, -45.27
	Min, Max	101.2, 809.3	-87.5, 0.4	343.6, 2288.3	-56.7, 149.2	84.5, 497.2	-82.6, -37.1
	Mean (SD)	403.47 (144.204)	-44.04 (23.202)	789.67 (451.453)	0.46 (38.612)	298.42 (165.286)	-60.14 (17.504)
	95% CI of Mean	351.47, 455.46	-52.87, -35.20	629.59, 949.75	-14.23, 15.15	160.24, 436.61	-74.78, -45.50

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=36)		mCC (N=34)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	33		30		7	
	Missing, n (%)	3 (8.3)		4 (11.8)		0	
	Geometric Mean (CV%)	718.48 (49.844)		731.46 (48.511)		530.58 (76.556)	
	95% CI of Geometric Mean	607.95, 849.09		616.07, 868.45		283.11, 994.36	
	Median	724.29		768.05		795.45	
	Q25, Q75	531.12, 1016.99		549.30, 929.79		315.12, 915.49	
	Min, Max	276.5, 2004.9		286.3, 1807.3		166.9, 918.1	
	Mean (SD)	797.88 (375.729)		807.91 (369.787)		626.23 (327.097)	
	95% CI of Mean	664.64, 931.11		669.83, 946.00		323.71, 928.75	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=36)		mCC (N=34)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	36	33	33	30	7	7
	Missing, n (%)	0	3 (8.3)	1 (2.9)	4 (11.8)	0	0
	Geometric Mean (CV%)	297.88 (60.886)		583.39 (65.324)		213.56 (79.069)	
	95% CI of Geometric Mean	246.33, 360.21		472.23, 720.71		112.10, 406.85	
	Median	311.46	-54.89	667.16	-19.50	237.95	-61.64
	Q25, Q75	188.46, 456.12	-68.95, -39.99	428.57, 833.33	-38.07, 7.61	132.56, 344.29	-70.09, -37.45
	Min, Max	86.6, 724.1	-84.7, 48.7	146.6, 1933.2	-53.5, 105.7	67.2, 572.7	-82.1, 1.9
	Mean (SD)	342.29 (170.995)	-51.12 (28.128)	682.95 (382.624)	-13.08 (35.023)	258.56 (167.074)	-53.75 (28.114)
	95% CI of Mean	284.43, 400.16	-61.10, -41.15	547.27, 818.63	-26.17, 0.00	104.04, 413.08	-79.75, -27.74

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=41)		mCC (N=31)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		29		7	
	Missing, n (%)	4 (9.8)		2 (6.5)		0	
	Geometric Mean (CV%)	745.06 (47.524)		727.91 (49.374)		530.58 (76.556)	
	95% CI of Geometric Mean	640.98, 866.04		609.42, 869.44		283.11, 994.36	
	Median	724.29		727.60		795.45	
	Q25, Q75	535.89, 1057.32		549.30, 929.79		315.12, 915.49	
	Min, Max	276.5, 2004.9		286.3, 1807.3		166.9, 918.1	
	Mean (SD)	821.12 (371.622)		806.73 (376.274)		626.23 (327.097)	
	95% CI of Mean	697.21, 945.03		663.59, 949.86		323.71, 928.75	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population****Parameter (units): 3-HPMA (ng/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=41)		mCC (N=31)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	41	37	31	29	7	7
	Missing, n (%)	0	4 (9.8)	0	2 (6.5)	0	0
	BLOQ, n (%)	0		0		1 (14.3)	
	Geometric Mean (CV%)	314.39 (39.787)		605.35 (83.499)		171.89 (118.161)	
	95% CI of Geometric Mean	278.55, 354.83		463.60, 790.44		72.40, 408.08	
	Median	314.85	-56.61	655.79	-8.55	251.33	-65.78
	Q25, Q75	233.66, 386.73	-65.78, -41.90	400.00, 982.30	-32.32, 14.07	174.04, 313.32	-71.65, -44.77
	Min, Max	115.6, 744.4	-89.4, -1.6	73.4, 1652.8	-81.3, 168.9	22.1, 318.1	-94.1, 8.3
	Mean (SD)	337.73 (133.136)	-53.94 (18.597)	745.27 (438.957)	-5.54 (48.286)	216.29 (102.639)	-57.40 (32.340)
	95% CI of Mean	295.70, 379.76	-60.14, -47.73	584.25, 906.28	-23.91, 12.84	121.36, 311.22	-87.31, -27.49

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	70	31	22
	Missing, n (%)	5 (6.7)	4 (11.4)	2 (8.3)
	Geometric Mean (CV%)	1206.40 (46.598)	1254.72 (47.842)	1138.82 (54.422)
	95% CI of Geometric Mean	1085.39, 1340.90	1062.24, 1482.07	908.61, 1427.35
	Median	1297.67	1207.25	1163.57
	Q25, Q75	852.10, 1650.43	976.13, 1670.49	957.28, 1687.61
	Min, Max	435.7, 2839.9	325.3, 3007.6	249.2, 2096.0
	Mean (SD)	1325.02 (574.575)	1377.95 (609.263)	1262.73 (518.069)
	95% CI of Mean	1188.02, 1462.03	1154.47, 1601.44	1033.03, 1492.43

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	466.68 (45.321)	1109.30 (63.411)	378.45 (38.332)
	95% CI of Geometric Mean	422.21, 515.84	908.48, 1354.50	322.45, 444.17
	Median	454.44	1097.54	380.02
	Q25, Q75	357.01, 682.54	848.36, 1479.35	292.58, 492.37
	Min, Max	171.3, 963.3	219.9, 2941.5	172.7, 688.8
	Mean (SD)	508.62 (202.987)	1278.39 (652.879)	403.31 (144.826)
	95% CI of Mean	461.58, 555.65	1054.12, 1502.67	340.68, 465.95

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	439.68 (37.855)	1079.16 (52.031)	306.48 (47.395)
	95% CI of Geometric Mean	403.94, 478.59	912.14, 1276.76	252.26, 372.35
	Median	428.78	992.46	306.54
	Q25, Q75	344.52, 557.82	814.64, 1479.35	264.02, 395.86
	Min, Max	167.4, 949.5	323.9, 2580.1	79.8, 615.7
	Mean (SD)	469.29 (171.904)	1208.40 (587.889)	333.80 (132.917)
	95% CI of Mean	429.46, 509.12	1006.45, 1410.35	276.32, 391.29

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	475.72 (40.676)	1193.33 (51.135)	261.31 (44.173)
	95% CI of Geometric Mean	434.48, 520.87	1011.25, 1408.20	217.69, 313.65
	Median	478.41	1282.91	291.81
	Q25, Q75	367.49, 630.94	849.30, 1542.24	210.01, 339.25
	Min, Max	152.5, 1056.7	255.4, 2766.4	62.3, 462.4
	Mean (SD)	511.28 (192.641)	1321.66 (584.914)	279.93 (90.899)
	95% CI of Mean	466.65, 555.92	1120.73, 1522.59	240.62, 319.24

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n (%)	0	0	1 (4.3)
	Geometric Mean (CV%)	463.40 (44.461)	1106.70 (55.812)	273.97 (61.375)
	95% CI of Geometric Mean	419.97, 511.32	925.42, 1323.48	214.54, 349.86
	Median	470.57	1159.94	311.69
	Q25, Q75	366.32, 595.64	811.18, 1479.35	223.03, 407.15
	Min, Max	136.1, 1282.8	235.7, 2735.2	34.0, 507.0
	Mean (SD)	504.37 (208.379)	1247.95 (606.151)	305.73 (118.268)
	95% CI of Mean	456.08, 552.65	1039.72, 1456.17	254.58, 356.88

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	489.28 (42.325)	1090.19 (68.647)	258.25 (55.336)
	95% CI of Geometric Mean	445.36, 537.53	880.64, 1349.59	206.52, 322.93
	Median	496.71	1129.72	325.90
	Q25, Q75	379.35, 645.78	830.49, 1520.40	191.40, 353.92
	Min, Max	137.5, 1358.1	127.3, 2973.4	79.5, 533.0
	Mean (SD)	529.04 (211.912)	1271.28 (668.077)	288.05 (120.572)
	95% CI of Mean	479.94, 578.14	1041.79, 1500.78	235.91, 340.20

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=32)	mCC (N=34)	SA (N=8)
		Value	Value	Value
Baseline	n	30	30	8
	Missing, n (%)	2 (6.3)	4 (11.8)	0
	Geometric Mean (CV%)	1208.12 (46.736)	1213.68 (51.561)	1075.59 (57.319)
	95% CI of Geometric Mean	1023.36, 1426.24	1012.42, 1454.93	688.85, 1679.45
	Median	1323.75	1185.74	1080.66
	Q25, Q75	837.08, 1651.30	972.51, 1670.49	628.88, 1733.07
	Min, Max	510.1, 2768.6	325.3, 3007.6	605.1, 2261.0
	Mean (SD)	1325.11 (571.525)	1351.21 (637.587)	1218.91 (656.761)
	95% CI of Mean	1111.69, 1538.52	1113.13, 1589.29	669.84, 1767.98

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=32)	mCC (N=34)	SA (N=8)
		Value	Value	Value
Day 30	n	32	34	8
	Geometric Mean (CV%)	602.90 (51.979)	1176.30 (57.065)	385.10 (43.554)
	95% CI of Geometric Mean	505.44, 719.15	977.37, 1415.71	271.80, 545.63
	Median	655.27	1077.30	360.75
	Q25, Q75	480.45, 819.13	815.86, 1647.36	274.27, 524.41
	Min, Max	99.8, 1370.2	400.1, 3460.4	248.2, 768.6
	Mean (SD)	663.04 (264.609)	1354.10 (780.002)	416.96 (186.390)
	95% CI of Mean	567.63, 758.45	1081.94, 1626.26	261.13, 572.79

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=36)	mCC (N=34)	SA (N=7)
		Value	Value	Value
Baseline	n	34	31	7
	Missing, n (%)	2 (5.6)	3 (8.8)	0
	Geometric Mean (CV%)	1197.49 (49.692)	1214.52 (50.593)	855.97 (81.144)
	95% CI of Geometric Mean	1016.44, 1410.77	1019.42, 1446.95	443.38, 1652.48
	Median	1188.11	1186.77	958.23
	Q25, Q75	837.08, 1749.04	972.51, 1670.49	605.10, 1370.15
	Min, Max	510.1, 2839.9	325.3, 3007.6	249.2, 2261.0
	Mean (SD)	1331.74 (630.193)	1347.62 (627.188)	1038.85 (660.769)
	95% CI of Mean	1111.85, 1551.63	1117.56, 1577.68	427.74, 1649.97

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=36)	mCC (N=34)	SA (N=7)
		Value	Value	Value
Day 60	n	36	34	7
	Geometric Mean (CV%)	474.37 (60.262)	989.72 (66.844)	352.90 (30.036)
	95% CI of Geometric Mean	392.94, 572.68	800.60, 1223.51	268.91, 463.13
	Median	552.62	1055.23	390.18
	Q25, Q75	348.35, 726.28	731.79, 1313.14	263.54, 459.36
	Min, Max	121.2, 1201.1	161.2, 3671.6	234.0, 500.5
	Mean (SD)	539.01 (246.377)	1165.30 (696.959)	365.80 (102.682)
	95% CI of Mean	455.64, 622.38	922.11, 1408.48	270.83, 460.77

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=41)	mCC (N=31)	SA (N=7)
		Value	Value	Value
Baseline	n	39	29	7
	Missing, n (%)	2 (4.9)	2 (6.5)	0
	Geometric Mean (CV%)	1184.30 (48.127)	1190.92 (51.096)	855.97 (81.144)
	95% CI of Geometric Mean	1021.42, 1373.16	991.55, 1430.37	443.38, 1652.48
	Median	1204.78	1184.71	958.23
	Q25, Q75	837.08, 1650.43	972.51, 1500.65	605.10, 1370.15
	Min, Max	510.1, 2839.9	325.3, 3007.6	249.2, 2261.0
	Mean (SD)	1309.85 (603.986)	1324.51 (629.863)	1038.85 (660.769)
	95% CI of Mean	1114.05, 1505.64	1084.91, 1564.10	427.74, 1649.97

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.3.3 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): 3-HPMA (ug)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=41)	mCC (N=31)	SA (N=7)
		Value	Value	Value
Day 90	n	41	31	7
	BLOQ, n (%)	0	0	1 (14.3)
	Geometric Mean (CV%)	517.58 (37.220)	1013.73 (84.591)	284.26 (88.336)
	95% CI of Geometric Mean	461.95, 579.91	774.26, 1327.27	140.82, 573.80
	Median	549.99	1119.19	336.00
	Q25, Q75	409.79, 670.76	657.93, 1708.44	208.05, 496.98
	Min, Max	228.7, 1063.4	87.9, 3131.6	60.5, 597.6
	Mean (SD)	550.20 (192.772)	1246.18 (735.658)	341.49 (176.431)
	95% CI of Mean	489.35, 611.05	976.33, 1516.03	178.31, 504.67

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		30		21	
	Missing, n (%)	10 (13.3)		5 (14.3)		3 (12.5)	
	Geometric Mean (CV%)	1510.14 (108.680)		1433.17 (107.941)		1488.78 (102.283)	
	95% CI of Geometric Mean	1213.34, 1879.53		1032.20, 1989.89		1012.87, 2188.30	
	Median	1776.79		1486.69		1624.50	
	Q25, Q75	1045.51, 2691.81		902.14, 3178.29		951.72, 2256.10	
	Min, Max	93.0, 9243.9		160.8, 4946.2		213.5, 8015.0	
	Mean (SD)	2088.90 (1665.760)		1946.08 (1392.191)		2020.19 (1712.810)	
	95% CI of Mean	1676.14, 2501.66		1426.22, 2465.94		1240.53, 2799.86	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	1 (1.4)		0		0	
	Geometric Mean (CV%)	694.93 (119.599)		1344.34 (134.554)		602.09 (136.564)	
	95% CI of Geometric Mean	555.99, 868.59		937.49, 1927.76		382.04, 948.89	
	Median	802.61	-52.46	1472.30	3.85	704.52	-53.20
	Q25, Q75	357.66, 1256.87	-65.15, -40.00	667.14, 3290.16	-26.63, 28.85	290.74, 1174.19	-71.96, -43.45
	Min, Max	47.2, 6220.9	-83.2, 129.5	91.3, 6110.2	-62.2, 101.1	58.3, 4532.2	-92.8, -12.2
	Mean (SD)	1041.71 (1065.440)	-48.31 (31.687)	1994.46 (1591.973)	6.02 (39.252)	935.97 (964.772)	-55.52 (20.790)
	95% CI of Mean	789.52, 1293.90	-56.17, -40.45	1429.96, 2558.95	-8.65, 20.68	508.21, 1363.73	-64.98, -46.05

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	1 (1.4)		0		1 (4.5)	
	Geometric Mean (CV%)	304.41 (102.054)		1224.38 (147.838)		241.86 (121.679)	
	95% CI of Geometric Mean	249.23, 371.80		835.90, 1793.39		158.50, 369.07	
	Median	292.52	-79.49	1347.42	-2.77	243.33	-83.45
	Q25, Q75	183.39, 509.11	-86.27, -70.91	564.49, 2956.52	-26.74, 15.32	142.86, 409.35	-86.53, -72.82
	Min, Max	32.2, 2512.8	-94.5, 36.9	117.8, 5703.9	-75.5, 150.8	25.9, 2178.2	-94.5, -68.2
	Mean (SD)	436.03 (448.332)	-75.51 (19.333)	1868.20 (1457.750)	3.10 (54.959)	373.46 (449.848)	-81.70 (7.728)
	95% CI of Mean	329.90, 542.15	-80.31, -70.72	1351.30, 2385.10	-17.42, 23.63	174.01, 572.92	-85.22, -78.17

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	1 (1.4)		0		1 (4.5)	
	Geometric Mean (CV%)	246.31 (95.700)		1295.86 (145.108)		190.44 (89.125)	
	95% CI of Geometric Mean	203.51, 298.11		888.43, 1890.13		135.68, 267.29	
	Median	240.52	-85.01	1701.39	-3.97	174.79	-87.43
	Q25, Q75	160.00, 369.17	-89.69, -77.85	593.71, 2886.79	-28.64, 34.62	127.93, 266.19	-89.74, -82.91
	Min, Max	24.5, 4261.7	-95.4, 276.4	118.4, 7010.7	-92.3, 147.0	37.4, 1492.7	-96.8, -40.1
	Mean (SD)	367.64 (560.635)	-75.83 (46.457)	1998.22 (1682.487)	7.91 (56.392)	265.10 (304.148)	-85.29 (11.399)
	95% CI of Mean	234.93, 500.34	-87.34, -64.31	1401.63, 2594.81	-13.16, 28.97	130.25, 399.96	-90.48, -80.10

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	1 (1.4)		0		1 (4.5)	
	Geometric Mean (CV%)	158.45 (88.790)		1307.80 (162.607)		135.71 (87.885)	
	95% CI of Geometric Mean	132.28, 189.79		873.82, 1957.29		97.03, 189.80	
	Median	142.73	-90.00	1790.54	-1.87	120.55	-91.62
	Q25, Q75	98.04, 248.90	-92.96, -86.67	1019.87, 2926.83	-30.90, 50.62	86.36, 196.70	-92.78, -88.22
	Min, Max	27.1, 954.9	-97.8, -21.4	50.1, 5475.4	-94.4, 142.7	32.8, 944.4	-96.7, -71.0
	Mean (SD)	213.59 (192.581)	-86.72 (11.765)	1991.15 (1464.129)	6.15 (49.555)	187.16 (202.313)	-89.59 (6.213)
	95% CI of Mean	168.00, 259.18	-89.64, -83.80	1471.99, 2510.32	-12.36, 24.66	97.46, 276.87	-92.43, -86.76

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	4 (5.6)		0		2 (9.1)	
	Geometric Mean (CV%)	133.64 (86.656)		1062.05 (189.124)		133.11 (99.339)	
	95% CI of Geometric Mean	111.94, 159.55		685.84, 1644.62		92.18, 192.21	
	Median	131.05	-91.16	1557.46	-0.64	123.18	-91.74
	Q25, Q75	81.06, 209.76	-93.96, -86.95	304.94, 2440.48	-54.04, 17.40	89.12, 216.43	-93.56, -87.62
	Min, Max	18.7, 1269.2	-98.5, -57.6	118.7, 6677.6	-91.2, 71.6	20.9, 1008.6	-97.2, -70.7
	Mean (SD)	180.95 (187.577)	-88.81 (8.745)	1888.20 (1785.587)	-12.55 (42.740)	189.32 (207.447)	-89.87 (6.267)
	95% CI of Mean	136.55, 225.36	-90.98, -86.64	1255.06, 2521.35	-28.52, 3.41	97.34, 281.30	-92.73, -87.01

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)**

Parameter (units): S-PMA (pg/mg creat)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	36		29		12	
	Missing, n (%)	4 (10.0)		5 (14.7)		1 (7.7)	
	Geometric Mean (CV%)	1414.89 (121.926)		1445.75 (110.347)		1477.17 (115.953)	
	95% CI of Geometric Mean	1024.41, 1954.21		1029.59, 2030.12		821.71, 2655.48	
	Median	1280.87		1458.80		1625.52	
	Q25, Q75	841.87, 2878.38		902.14, 3178.29		880.72, 2436.98	
	Min, Max	93.0, 9243.9		160.8, 4946.2		310.0, 8015.0	
	Mean (SD)	2076.14 (1887.805)		1974.06 (1407.396)		2140.87 (2097.308)	
	95% CI of Mean	1437.40, 2714.89		1438.71, 2509.41		808.30, 3473.44	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	39	36	32	29	13	12
	Missing, n (%)	1 (2.5)	4 (10.0)	2 (5.9)	5 (14.7)	0	1 (7.7)
	BLOQ, n (%)	0		0		1 (7.7)	
	Geometric Mean (CV%)	320.57 (175.349)		1402.80 (155.739)		329.61 (294.050)	
	95% CI of Geometric Mean	218.30, 470.75		940.26, 2092.85		132.70, 818.67	
	Median	280.36	-74.63	2161.42	4.91	190.78	-75.91
	Q25, Q75	122.16, 822.41	-90.64, -50.93	702.41, 3354.25	-14.02, 24.27	88.32, 1384.62	-93.70, -60.47
	Min, Max	43.7, 3691.9	-99.1, 197.4	77.4, 5188.9	-86.2, 208.5	35.9, 3307.4	-96.9, 125.4
	Mean (SD)	602.09 (728.708)	-59.96 (55.004)	2130.86 (1521.784)	15.56 (60.720)	844.62 (1100.315)	-56.83 (63.352)
	95% CI of Mean	365.86, 838.31	-78.58, -41.35	1582.19, 2679.53	-7.54, 38.66	179.70, 1509.54	-97.08, -16.57

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	35		30		11	
	Missing, n (%)	4 (10.3)		5 (14.3)		1 (8.3)	
	Geometric Mean (CV%)	1457.69 (116.975)		1448.78 (107.603)		1029.77 (117.813)	
	95% CI of Geometric Mean	1059.59, 2005.35		1044.20, 2010.13		550.21, 1927.30	
	Median	1238.36		1488.19		1385.92	
	Q25, Q75	755.63, 2835.20		902.14, 3178.29		358.61, 1991.98	
	Min, Max	93.0, 9243.9		160.8, 4946.2		213.5, 3742.5	
	Mean (SD)	2122.54 (1944.977)		1959.58 (1385.190)		1436.98 (1101.874)	
	95% CI of Mean	1454.41, 2790.67		1442.33, 2476.82		696.72, 2177.23	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	35	33	30	11	11
	Missing, n (%)	0	4 (10.3)	2 (5.7)	5 (14.3)	1 (8.3)	1 (8.3)
	BLOQ, n (%)	0		0		1 (9.1)	
	Geometric Mean (CV%)	330.16 (161.282)		1152.49 (139.241)		230.52 (278.640)	
	95% CI of Geometric Mean	228.75, 476.53		797.53, 1665.43		85.67, 620.27	
	Median	300.37	-77.64	1318.51	-19.25	256.34	-77.98
	Q25, Q75	145.21, 793.10	-91.80, -56.40	481.22, 2313.33	-43.79, 54.28	53.57, 509.30	-92.75, -41.74
	Min, Max	30.3, 3810.7	-98.6, 264.5	127.1, 8145.4	-90.2, 186.7	18.7, 3909.1	-98.1, 166.4
	Mean (SD)	582.60 (682.622)	-59.95 (64.071)	1789.31 (1698.957)	-0.40 (58.640)	614.52 (1121.768)	-50.57 (75.367)
	95% CI of Mean	361.32, 803.89	-81.96, -37.93	1186.88, 2391.74	-22.30, 21.51	-139.10, 1368.14	-101.21, 0.07

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	43		29		9	
	Missing, n (%)	4 (8.5)		3 (9.4)		0	
	Geometric Mean (CV%)	1479.21 (115.123)		1397.51 (106.313)		937.34 (134.139)	
	95% CI of Geometric Mean	1114.94, 1962.50		1003.91, 1945.42		429.73, 2044.54	
	Median	1478.47		1458.80		951.72	
	Q25, Q75	758.62, 2921.57		902.14, 2500.00		358.61, 1991.98	
	Min, Max	93.0, 9243.9		160.8, 4946.2		213.5, 3742.5	
	Mean (SD)	2108.49 (1811.357)		1885.10 (1347.191)		1404.14 (1225.195)	
	95% CI of Mean	1551.03, 2665.95		1372.65, 2397.55		462.36, 2345.91	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	43	32	29	9	9
	Missing, n (%)	0	4 (8.5)	0	3 (9.4)	0	
	BLOQ, n (%)	1 (2.1)		0		1 (11.1)	
	Geometric Mean (CV%)	314.02 (184.385)		1218.56 (151.051)		181.62 (179.279)	
	95% CI of Geometric Mean	219.66, 448.93		822.54, 1805.25		72.23, 456.60	
	Median	330.20	-81.14	1438.46	-6.58	202.61	-74.98
	Q25, Q75	129.85, 674.80	-93.46, -37.57	500.00, 2774.07	-28.49, 33.45	74.46, 296.06	-91.08, -65.12
	Min, Max	25.7, 4007.9	-98.8, 21.2	127.1, 7266.2	-80.6, 180.9	27.7, 1960.5	-97.6, 33.6
	Mean (SD)	616.46 (790.960)	-65.24 (34.888)	1944.16 (1732.798)	5.54 (63.015)	371.86 (603.701)	-64.63 (41.226)
	95% CI of Mean	384.22, 848.70	-75.98, -54.50	1319.42, 2568.91	-18.43, 29.52	-92.19, 835.91	-96.32, -32.93

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	67	30	21
	Missing, n (%)	8 (10.7)	5 (14.3)	3 (12.5)
	Geometric Mean (CV%)	2509.60 (97.261)	2272.12 (111.126)	2387.22 (105.035)
	95% CI of Geometric Mean	2056.68, 3062.24	1625.56, 3175.85	1612.26, 3534.68
	Median	2616.89	2711.77	3141.39
	Q25, Q75	1626.01, 4482.08	1499.78, 4741.20	1650.05, 3917.16
	Min, Max	230.2, 10411.1	308.5, 6707.6	318.7, 8650.3
	Mean (SD)	3320.29 (2395.195)	3071.19 (2009.484)	3173.02 (2202.545)
	95% CI of Mean	2736.05, 3904.53	2320.83, 3821.54	2170.43, 4175.61

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	1 (1.4)	0	0
	Geometric Mean (CV%)	1136.98 (108.284)	2165.27 (136.353)	972.52 (132.196)
	95% CI of Geometric Mean	923.01, 1400.56	1505.47, 3114.24	622.74, 1518.74
	Median	1153.75	2735.68	988.54
	Q25, Q75	688.90, 2118.49	1024.99, 5610.46	679.91, 2188.27
	Min, Max	61.4, 5654.7	224.1, 8360.3	76.7, 4693.4
	Mean (SD)	1570.84 (1226.997)	3192.92 (2371.520)	1436.36 (1213.066)
	95% CI of Mean	1280.41, 1861.27	2352.01, 4033.83	898.52, 1974.21

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	1 (1.4)	0	1 (4.5)
	Geometric Mean (CV%)	499.81 (95.348)	2001.45 (147.487)	379.88 (111.694)
	95% CI of Geometric Mean	413.18, 604.60	1367.15, 2930.03	254.89, 566.15
	Median	539.34	2534.95	367.72
	Q25, Q75	307.94, 798.81	900.69, 4624.00	195.69, 671.93
	Min, Max	63.1, 3560.3	172.5, 8233.7	46.4, 2301.2
	Mean (SD)	677.68 (612.725)	3047.05 (2321.098)	548.52 (519.242)
	95% CI of Mean	532.65, 822.71	2224.02, 3870.08	318.30, 778.74

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	1 (1.4)	0	1 (4.5)
	Geometric Mean (CV%)	402.95 (88.056)	2095.72 (144.027)	294.07 (81.062)
	95% CI of Geometric Mean	336.79, 482.10	1439.24, 3051.62	214.58, 402.99
	Median	416.02	3179.08	327.67
	Q25, Q75	290.86, 601.55	848.24, 4467.60	163.61, 435.77
	Min, Max	54.2, 5041.0	165.8, 10156.7	84.8, 1462.9
	Mean (SD)	554.48 (677.191)	3167.52 (2410.120)	374.52 (298.918)
	95% CI of Mean	394.19, 714.78	2312.93, 4022.12	241.99, 507.06

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	1 (1.4)	0	1 (4.5)
	Geometric Mean (CV%)	261.33 (79.467)	2085.41 (154.536)	212.78 (75.027)
	95% CI of Geometric Mean	221.44, 308.40	1409.54, 3085.34	158.21, 286.16
	Median	243.98	2496.96	215.28
	Q25, Q75	171.14, 424.72	968.86, 4896.36	129.92, 322.67
	Min, Max	50.6, 1391.4	86.2, 7708.9	74.0, 1035.0
	Mean (SD)	335.66 (272.318)	3129.41 (2209.487)	270.19 (229.588)
	95% CI of Mean	271.20, 400.12	2345.95, 3912.86	168.39, 371.99

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	4 (5.6)	0	2 (9.1)
	Geometric Mean (CV%)	226.72 (78.949)	1740.95 (180.388)	221.98 (89.625)
	95% CI of Geometric Mean	192.28, 267.33	1136.29, 2667.37	157.92, 312.01
	Median	225.22	2436.79	220.96
	Q25, Q75	153.06, 332.67	427.52, 5015.40	130.46, 300.72
	Min, Max	28.1, 1918.0	161.1, 7658.7	31.4, 1072.0
	Mean (SD)	290.66 (264.015)	2961.66 (2463.585)	290.23 (238.344)
	95% CI of Mean	228.16, 353.15	2088.10, 3835.21	184.55, 395.91

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	37	29	12
	Missing, n (%)	3 (7.5)	5 (14.7)	1 (7.7)
	Geometric Mean (CV%)	2326.79 (107.401)	2370.46 (110.394)	2314.18 (113.176)
	95% CI of Geometric Mean	1737.54, 3115.88	1687.95, 3328.92	1299.66, 4120.63
	Median	2350.87	2808.69	2918.66
	Q25, Q75	1527.97, 4520.10	1503.88, 4741.20	1474.63, 4089.66
	Min, Max	230.2, 10411.1	308.5, 6707.6	452.0, 8650.3
	Mean (SD)	3230.99 (2638.523)	3167.54 (1991.755)	3147.94 (2325.108)
	95% CI of Mean	2351.25, 4110.72	2409.91, 3925.17	1670.63, 4625.25

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Day 30	n	39	32	13
	Missing, n (%)	1 (2.5)	2 (5.9)	0
	BLOQ, n (%)	0	0	1 (7.7)
	Geometric Mean (CV%)	515.36 (185.502)	2342.97 (142.576)	541.39 (275.589)
	95% CI of Geometric Mean	346.90, 765.62	1602.64, 3425.28	223.14, 1313.50
	Median	476.14	3800.51	295.48
	Q25, Q75	204.25, 1392.42	1054.80, 5424.94	171.35, 2466.95
	Min, Max	37.9, 5209.5	198.8, 6777.5	105.2, 6364.1
	Mean (SD)	992.09 (1146.327)	3410.54 (2208.643)	1368.51 (1860.861)
	95% CI of Mean	620.49, 1363.69	2614.24, 4206.85	244.00, 2493.02

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	37	30	11
	Missing, n (%)	2 (5.1)	5 (14.3)	1 (8.3)
	Geometric Mean (CV%)	2465.08 (97.075)	2359.91 (107.696)	1667.23 (130.944)
	95% CI of Geometric Mean	1878.65, 3234.57	1700.55, 3274.92	851.97, 3262.59
	Median	2287.43	2726.79	2365.54
	Q25, Q75	1577.39, 4520.10	1503.88, 4741.20	500.22, 3917.16
	Min, Max	230.2, 10411.1	308.5, 6707.6	318.7, 5662.0
	Mean (SD)	3327.64 (2681.613)	3131.07 (1967.279)	2391.11 (1757.726)
	95% CI of Mean	2433.54, 4221.74	2396.48, 3865.67	1210.25, 3571.98

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Day 60	n	39	33	11
	Missing, n (%)	0	2 (5.7)	1 (8.3)
	BLOQ, n (%)	0	0	1 (9.1)
	Geometric Mean (CV%)	536.30 (140.309)	1931.34 (150.576)	385.05 (266.338)
	95% CI of Geometric Mean	382.43, 752.08	1313.09, 2840.67	145.74, 1017.23
	Median	502.22	2533.96	392.77
	Q25, Q75	224.22, 1294.08	913.50, 4476.13	72.83, 1130.70
	Min, Max	55.5, 4550.5	76.5, 8675.5	60.7, 6281.0
	Mean (SD)	862.10 (864.460)	2924.90 (2270.225)	1023.91 (1811.479)
	95% CI of Mean	581.87, 1142.33	2119.90, 3729.89	-193.06, 2240.89

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	45	29	9
	Missing, n (%)	2 (4.3)	3 (9.4)	0
	Geometric Mean (CV%)	2457.64 (101.539)	2286.44 (107.337)	1520.28 (151.728)
	95% CI of Geometric Mean	1908.49, 3164.81	1638.83, 3189.97	656.23, 3521.98
	Median	2350.87	2644.89	1888.23
	Q25, Q75	1577.39, 4520.10	1503.88, 4407.76	500.22, 3917.16
	Min, Max	230.2, 10411.1	308.5, 6707.6	318.7, 5662.0
	Mean (SD)	3326.41 (2562.949)	3035.44 (1929.822)	2360.09 (1961.943)
	95% CI of Mean	2556.41, 4096.41	2301.37, 3769.51	852.00, 3868.18

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1 Descriptive Statistics of S-PMA in 24-hour Urine Collection - PP Set)**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Day 90	n	47	32	9
	BLOQ, n (%)	1 (2.1)	0	1 (11.1)
	Geometric Mean (CV%)	526.90 (186.138)	2023.19 (141.813)	310.88 (203.176)
	95% CI of Geometric Mean	367.92, 754.59	1385.61, 2954.15	116.35, 830.66
	Median	534.45	2690.65	316.57
	Q25, Q75	214.50, 1520.64	817.28, 4512.55	89.67, 609.15
	Min, Max	47.1, 5350.4	204.7, 8700.6	75.6, 4004.4
	Mean (SD)	1037.50 (1267.335)	3067.68 (2401.243)	722.53 (1251.719)
	95% CI of Mean	665.39, 1409.61	2201.94, 3933.43	-239.63, 1684.69

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.1 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Baseline	n	39	26	16	14	12	9
	Missing, n (%)	7 (15.2)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Geometric Mean (CV%)	1271.20 (108.202)	1955.33 (100.944)	1275.18 (106.892)	1637.84 (111.508)	1062.83 (92.067)	2333.40 (85.455)
	95% CI of Geometric Mean	955.58, 1691.06	1393.75, 2743.18	800.85, 2030.42	974.70, 2752.14	646.04, 1748.51	1320.70, 4122.62
	Median	1279.17	2023.67	1408.79	1497.71	1263.71	2256.10
	Q25, Q75	755.63, 2636.82	1070.06, 3594.16	854.58, 2288.83	1053.96, 4045.45	811.94, 1743.70	1783.58, 3641.98
	Min, Max	93.0, 5614.9	226.9, 9243.9	160.8, 3984.5	240.1, 4946.2	213.5, 3448.3	545.9, 8015.0
	Mean (SD)	1731.94 (1294.123)	2624.35 (2015.140)	1690.55 (1158.244)	2238.11 (1613.550)	1341.25 (874.982)	2925.45 (2160.611)
	95% CI of Mean	1312.43, 2151.45	1810.42, 3438.29	1073.36, 2307.74	1306.47, 3169.75	785.31, 1897.19	1264.65, 4586.25

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.1 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 1	n	42	29	18	15	13	9
	Missing, n (%)	4 (8.7)	0	2 (10.0)	0	2 (13.3)	0
	BLOQ, n (%)	0	1 (3.4)	0	0	0	0
	Geometric Mean (CV%)	579.01 (109.731)	905.16 (124.959)	1150.43 (146.277)	1620.66 (121.223)	410.77 (138.639)	1045.99 (88.031)
	95% CI of Geometric Mean	438.90, 763.84	625.90, 1309.00	675.84, 1958.25	957.23, 2743.87	219.70, 768.01	584.32, 1872.38
	Median	632.76	859.77	1528.73	1472.30	401.35	1021.28
	Q25, Q75	330.59, 1101.69	510.82, 1748.88	624.30, 2234.04	1053.96, 3555.93	232.88, 1123.66	800.35, 1448.66
	Min, Max	68.7, 2891.0	47.2, 6220.9	91.3, 4085.9	264.2, 6110.2	58.3, 1666.7	290.7, 4532.2
	Mean (SD)	821.31 (699.903)	1360.92 (1393.633)	1728.37 (1351.932)	2313.76 (1836.632)	631.90 (567.636)	1375.18 (1262.036)
	95% CI of Mean	603.20, 1039.42	830.80, 1891.03	1056.06, 2400.67	1296.67, 3330.86	288.88, 974.93	405.09, 2345.28

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.1 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 1	n	39	26	16	14	12	9
	Missing, n (%)	7 (15.2)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-54.45	-52.10	18.58	-1.14	-65.56	-46.74
	Q25, Q75	-66.00, -39.44	-61.24, -40.00	-17.81, 29.40	-31.11, 28.85	-73.09, -48.63	-65.87, -42.84
	Min, Max	-81.0, 129.5	-83.2, 39.2	-46.3, 74.6	-62.2, 101.1	-92.8, -12.2	-78.6, -30.4
	Mean (SD)	-49.22 (34.349)	-46.95 (27.816)	9.20 (35.530)	2.38 (44.201)	-58.04 (23.873)	-52.16 (16.572)
	95% CI of Mean	-60.36, -38.08	-58.19, -35.71	-9.74, 28.14	-23.15, 27.91	-73.21, -42.86	-64.90, -39.41

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.1 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 2	n	42	29	18	15	13	9
	Missing, n (%)	4 (8.7)	0	2 (10.0)	0	2 (13.3)	0
	BLOQ, n (%)	0	1 (3.4)	0	0	1 (7.7)	0
	Geometric Mean (CV%)	257.52 (98.014)	387.85 (100.245)	1045.23 (141.992)	1480.33 (156.369)	163.15 (106.953)	427.10 (93.198)
	95% CI of Geometric Mean	199.42, 332.56	282.41, 532.65	619.85, 1762.52	799.60, 2740.61	96.25, 276.56	232.58, 784.31
	Median	257.32	483.54	1243.33	2205.44	185.38	405.94
	Q25, Q75	173.82, 425.00	228.99, 688.46	564.49, 2064.00	479.54, 3448.28	134.03, 275.00	253.79, 660.15
	Min, Max	32.2, 2512.8	69.1, 2220.5	117.8, 4338.2	134.9, 5703.9	25.9, 577.7	173.8, 2178.2
	Mean (SD)	370.32 (434.288)	531.19 (458.777)	1561.86 (1259.847)	2235.82 (1632.309)	220.78 (170.658)	594.00 (628.427)
	95% CI of Mean	234.98, 505.66	356.68, 705.70	935.34, 2188.37	1331.87, 3139.77	117.65, 323.91	110.94, 1077.06

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.1 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 2	n	39	26	16	14	12	9
	Missing, n (%)	7 (15.2)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-80.68	-78.96	-9.31	-2.44	-83.86	-81.87
	Q25, Q75	-87.48, -73.86	-84.89, -70.65	-25.57, 17.67	-29.18, 15.32	-86.51, -83.01	-86.53, -72.15
	Min, Max	-92.7, 36.9	-94.5, -53.0	-70.7, 142.1	-75.5, 150.8	-94.5, -69.0	-93.2, -68.2
	Mean (SD)	-74.38 (23.766)	-77.21 (9.660)	4.75 (55.947)	1.22 (55.851)	-83.19 (6.876)	-79.71 (8.746)
	95% CI of Mean	-82.09, -66.67	-81.12, -73.30	-25.07, 34.57	-31.03, 33.47	-87.57, -78.82	-86.43, -72.98

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.1 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 3	n	42	29	18	15	13	9
	Missing, n (%)	4 (8.7)	0	2 (10.0)	0	2 (13.3)	0
	BLOQ, n (%)	0	1 (3.4)	0	0	1 (7.7)	0
	Geometric Mean (CV%)	220.34 (95.269)	289.46 (94.091)	1145.37 (120.549)	1502.78 (181.518)	161.19 (65.867)	242.29 (119.159)
	95% CI of Geometric Mean	171.52, 283.05	213.81, 391.86	715.08, 1834.58	770.10, 2932.53	112.15, 231.69	117.62, 499.06
	Median	204.64	339.71	1782.90	1676.58	162.66	266.19
	Q25, Q75	160.00, 279.19	168.15, 432.43	593.71, 2326.80	465.70, 4289.19	127.93, 223.30	130.83, 289.06
	Min, Max	24.5, 4261.7	35.0, 1245.7	167.7, 3265.7	118.4, 7010.7	37.4, 504.7	66.6, 1492.7
	Mean (SD)	362.05 (698.932)	375.74 (265.236)	1577.22 (1015.515)	2503.42 (2171.802)	187.74 (112.053)	376.85 (447.457)
	95% CI of Mean	144.24, 579.85	274.84, 476.63	1072.22, 2082.23	1300.71, 3706.13	120.02, 255.45	32.90, 720.80

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.1 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 3	n	39	26	16	14	12	9
	Missing, n (%)	7 (15.2)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-86.03	-84.65	-3.97	-5.64	-87.34	-87.94
	Q25, Q75	-91.06, -73.70	-86.90, -81.77	-21.63, 53.17	-33.38, 21.03	-88.76, -83.76	-92.66, -81.38
	Min, Max	-95.3, 276.4	-95.4, -67.3	-84.4, 132.3	-92.3, 147.0	-94.7, -40.1	-96.8, -80.3
	Mean (SD)	-70.45 (59.467)	-83.90 (6.072)	11.33 (55.953)	4.00 (58.743)	-83.48 (14.042)	-87.70 (6.506)
	95% CI of Mean	-89.73, -51.16	-86.36, -81.44	-18.49, 41.15	-29.92, 37.92	-92.41, -74.56	-92.70, -82.69

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.1 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 4	n	42	29	18	15	13	9
	Missing, n (%)	4 (8.7)	0	2 (10.0)	0	2 (13.3)	0
	BLOQ, n (%)	0	1 (3.4)	0	0	1 (7.7)	0
	Geometric Mean (CV%)	135.98 (87.870)	197.73 (83.557)	1049.31 (190.801)	1703.37 (126.416)	99.23 (60.931)	213.30 (94.626)
	95% CI of Geometric Mean	107.42, 172.13	149.92, 260.80	566.68, 1942.96	991.52, 2926.26	70.66, 139.36	115.35, 394.41
	Median	125.98	232.81	1776.73	2172.66	113.25	185.07
	Q25, Q75	90.88, 192.81	124.07, 310.94	576.22, 2138.11	1053.96, 3859.22	68.75, 151.85	111.74, 244.19
	Min, Max	27.1, 954.9	28.3, 895.7	50.1, 4224.0	228.0, 5475.4	32.8, 229.1	86.4, 944.4
	Mean (SD)	188.74 (200.047)	249.58 (178.470)	1650.39 (1169.401)	2400.07 (1706.119)	113.45 (58.083)	293.64 (284.249)
	95% CI of Mean	126.40, 251.08	181.69, 317.47	1068.86, 2231.93	1455.24, 3344.89	78.34, 148.55	75.14, 512.14

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.1 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 4	n	39	26	16	14	12	9
	Missing, n (%)	7 (15.2)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-90.30	-89.38	-4.66	2.64	-91.91	-89.18
	Q25, Q75	-94.15, -84.52	-91.12, -87.46	-24.31, 53.80	-32.93, 25.85	-92.75, -86.92	-94.50, -88.22
	Min, Max	-97.8, -21.4	-97.0, -72.5	-94.4, 70.3	-58.7, 142.7	-96.7, -71.0	-95.9, -79.5
	Mean (SD)	-85.35 (14.576)	-88.77 (4.911)	4.93 (45.660)	7.55 (55.395)	-89.55 (7.031)	-89.65 (5.341)
	95% CI of Mean	-90.08, -80.62	-90.76, -86.78	-19.41, 29.26	-24.44, 39.53	-94.02, -85.08	-93.76, -85.53

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.1 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 5	n	42	29	18	15	13	9
	Missing, n (%)	4 (8.7)	0	2 (10.0)	0	2 (13.3)	0
	BLOQ, n (%)	3 (7.1)	1 (3.4)	0	0	2 (15.4)	0
	Geometric Mean (CV%)	110.44 (85.986)	176.16 (76.039)	879.32 (175.344)	1332.13 (207.650)	97.22 (89.166)	209.57 (83.843)
	95% CI of Geometric Mean	87.58, 139.26	136.24, 227.78	487.72, 1585.34	651.25, 2724.84	61.23, 154.34	119.60, 367.21
	Median	108.46	201.28	1109.05	1672.27	96.33	181.51
	Q25, Q75	77.37, 157.58	113.46, 242.66	266.94, 2403.20	304.94, 4226.19	56.67, 123.70	147.23, 275.99
	Min, Max	18.7, 1269.2	39.3, 761.5	119.5, 4951.8	118.7, 6677.6	20.9, 406.3	89.1, 1008.6
	Mean (SD)	155.08 (202.638)	218.42 (159.306)	1482.62 (1347.466)	2374.90 (2148.851)	126.60 (103.207)	279.92 (285.237)
	95% CI of Mean	91.93, 218.23	157.82, 279.02	812.54, 2152.71	1184.90, 3564.90	64.23, 188.97	60.66, 499.18

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.1 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 5	n	39	26	16	14	12	9
	Missing, n (%)	7 (15.2)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-91.70	-89.86	-9.88	2.23	-91.94	-91.74
	Q25, Q75	-95.29, -85.66	-92.58, -87.63	-36.56, 16.21	-56.69, 21.04	-93.81, -87.78	-93.50, -87.42
	Min, Max	-98.5, -57.6	-97.5, -59.1	-91.2, 27.2	-86.8, 71.6	-97.2, -70.7	-95.7, -80.5
	Mean (SD)	-88.67 (9.741)	-89.01 (7.176)	-14.98 (36.344)	-9.78 (50.352)	-89.91 (6.966)	-89.81 (5.609)
	95% CI of Mean	-91.84, -85.51	-91.92, -86.11	-34.35, 4.39	-38.86, 19.30	-94.34, -85.48	-94.12, -85.49

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.1 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=28)	Females (N=19)	Males (N=19)	Females (N=13)	Males (N=7)	Females (N=2)
Baseline	n	26	17	17	12	7	2
	Missing, n (%)	2 (7.1)	2 (10.5)	2 (10.5)	1 (7.7)	0	0
	Geometric Mean (CV%)	1251.49 (122.639)	1910.16 (97.288)	1285.31 (102.231)	1573.42 (116.566)	658.10 (101.544)	3232.36 (20.947)
	95% CI of Geometric Mean	849.89, 1842.85	1255.56, 2906.04	832.02, 1985.55	873.43, 2834.41	302.12, 1433.50	502.27, 20801.56
	Median	1236.37	1931.33	1458.80	1497.71	809.73	3267.13
	Q25, Q75	755.63, 2691.81	1052.63, 3368.42	902.14, 2077.67	955.07, 3767.07	310.00, 1467.46	2791.80, 3742.45
	Min, Max	93.0, 5614.9	567.7, 9243.9	160.8, 3984.5	240.1, 4946.2	213.5, 1992.0	2791.8, 3742.5
	Mean (SD)	1776.90 (1388.148)	2615.63 (2269.330)	1676.92 (1122.872)	2180.01 (1619.874)	871.85 (662.345)	3267.13 (672.216)
	95% CI of Mean	1216.21, 2337.59	1448.84, 3782.42	1099.59, 2254.25	1150.79, 3209.24	259.28, 1484.43	-2772.50, 9306.75

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.1 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=28)	Females (N=19)	Males (N=19)	Females (N=13)	Males (N=7)	Females (N=2)
Day 90	n	28	19	19	13	7	2
	BLOQ, n (%)	1 (3.6)	0	0	0	1 (14.3)	0
	Geometric Mean (CV%)	280.09 (209.128)	371.66 (153.812)	989.33 (142.471)	1652.44 (156.469)	206.60 (216.263)	115.67 (87.206)
	95% CI of Geometric Mean	169.40, 463.10	218.54, 632.06	595.60, 1643.35	843.59, 3236.81	61.07, 698.89	0.13, 99482.48
	Median	343.62	263.70	1187.40	2381.73	222.60	132.41
	Q25, Q75	107.49, 627.20	162.44, 1098.40	384.96, 2042.25	736.98, 3757.36	74.46, 298.08	67.96, 196.87
	Min, Max	25.7, 2620.7	66.3, 4007.9	127.1, 4403.8	171.1, 7266.2	27.7, 1960.5	68.0, 196.9
	Mean (SD)	565.68 (685.031)	691.30 (940.734)	1524.58 (1323.073)	2557.39 (2108.266)	440.27 (678.221)	132.41 (91.149)
	95% CI of Mean	300.05, 831.31	237.87, 1144.72	886.88, 2162.29	1283.37, 3831.41	-186.98, 1067.53	-686.53, 951.36

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.1 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=28)	Females (N=19)	Males (N=19)	Females (N=13)	Males (N=7)	Females (N=2)
%Change from baseline to Day 90	n	26	17	17	12	7	2
	Missing, n (%)	2 (7.1)	2 (10.5)	2 (10.5)	1 (7.7)	0	0
	Median	-72.18	-81.37	-15.31	4.63	-68.68	-96.15
	Q25, Q75	-92.66, -58.65	-93.46, -37.57	-30.65, 33.45	-21.58, 50.00	-85.14, -37.93	-97.57, -94.74
	Min, Max	-96.8, 21.2	-98.8, 12.1	-80.6, 180.9	-75.5, 119.2	-91.1, 33.6	-97.6, -94.7
	Mean (SD)	-64.86 (34.405)	-65.82 (36.674)	1.27 (70.180)	11.59 (53.626)	-55.62 (42.889)	-96.15 (1.998)
	95% CI of Mean	-78.76, -50.96	-84.68, -46.96	-34.82, 37.36	-22.48, 45.67	-95.29, -15.95	-114.11, -78.19

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.2 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Baseline	n	37	28	17	13	11	10
	Missing, n (%)	6 (14.0)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Geometric Mean (CV%)	1234.01 (105.696)	1971.98 (102.557)	1623.92 (83.234)	1217.12 (143.051)	1167.31 (104.158)	1945.54 (92.962)
	95% CI of Geometric Mean	924.50, 1647.13	1419.50, 2739.49	1118.30, 2358.14	643.19, 2303.17	656.29, 2076.23	1106.26, 3421.56
	Median	1238.36	2023.67	1539.63	1211.14	1470.05	1932.87
	Q25, Q75	925.12, 2390.85	1196.72, 3975.81	1265.69, 2345.39	699.00, 3178.29	809.73, 2065.38	1141.51, 3448.28
	Min, Max	93.0, 4638.4	350.3, 9243.9	288.5, 4946.2	160.8, 4350.6	213.5, 3742.5	545.9, 8015.0
	Mean (SD)	1643.17 (1129.700)	2677.91 (2059.985)	2028.40 (1351.559)	1838.44 (1492.048)	1517.48 (996.293)	2573.18 (2183.535)
	95% CI of Mean	1266.51, 2019.84	1879.12, 3476.69	1333.48, 2723.31	936.80, 2740.08	848.15, 2186.80	1011.17, 4135.19

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.2 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Day 1	n	40	31	19	14	12	10
	Missing, n (%)	3 (7.0)	1 (3.1)	1 (5.0)	1 (6.7)	1 (7.7)	1 (9.1)
	BLOQ, n (%)	1 (2.5)	0	0	0	0	0
	Geometric Mean (CV%)	536.66 (112.610)	970.00 (111.057)	1364.82 (122.801)	1317.05 (159.995)	459.05 (142.579)	833.72 (119.197)
	95% CI of Geometric Mean	401.79, 716.79	698.19, 1347.63	859.71, 2166.68	687.14, 2524.38	235.07, 896.44	425.50, 1633.57
	Median	540.32	926.57	1422.62	1568.27	622.90	814.99
	Q25, Q75	337.94, 915.84	575.22, 1802.12	953.85, 2340.91	482.66, 4042.55	236.10, 1089.76	370.73, 1666.67
	Min, Max	47.2, 2618.0	119.1, 6220.9	91.3, 5312.5	212.8, 6110.2	58.3, 1635.9	232.9, 4532.2
	Mean (SD)	759.93 (641.186)	1405.31 (1368.130)	1880.75 (1358.154)	2148.78 (1907.850)	675.56 (503.399)	1248.47 (1289.647)
	95% CI of Mean	554.86, 964.99	903.47, 1907.15	1226.13, 2535.36	1047.21, 3250.34	355.71, 995.41	325.90, 2171.03

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.2 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
%Change from baseline to Day 1	n	37	28	17	13	11	10
	Missing, n (%)	6 (14.0)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-60.89	-50.74	-2.28	28.56	-53.20	-57.63
	Q25, Q75	-72.90, -40.00	-58.73, -39.94	-26.63, 19.02	-20.13, 40.44	-75.29, -42.84	-67.52, -43.45
	Min, Max	-81.1, 129.5	-83.2, 39.2	-46.3, 74.6	-62.2, 101.1	-92.8, -12.2	-72.0, -30.4
	Mean (SD)	-50.01 (36.509)	-46.06 (24.362)	-1.74 (32.549)	16.16 (45.979)	-56.08 (25.623)	-54.89 (15.172)
	95% CI of Mean	-62.19, -37.83	-55.52, -36.61	-18.48, 15.00	-11.63, 43.95	-73.30, -38.86	-65.75, -44.03

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.2 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Day 2	n	40	31	19	14	12	10
	Missing, n (%)	3 (7.0)	1 (3.1)	1 (5.0)	1 (6.7)	1 (7.7)	1 (9.1)
	BLOQ, n (%)	1 (2.5)	0	0	0	1 (8.3)	0
	Geometric Mean (CV%)	256.40 (100.218)	379.88 (97.821)	1324.49 (127.242)	1100.51 (186.309)	169.27 (116.186)	371.15 (100.886)
	95% CI of Geometric Mean	196.37, 334.76	281.26, 513.07	825.37, 2125.41	542.90, 2230.80	94.08, 304.54	203.81, 675.85
	Median	238.31	430.11	1954.02	1294.61	198.32	256.71
	Q25, Q75	174.50, 395.47	223.79, 617.46	564.49, 2865.03	387.34, 3448.28	105.08, 351.12	188.71, 660.15
	Min, Max	32.2, 2512.8	67.7, 2220.5	135.0, 5703.9	117.8, 4138.5	25.9, 577.7	173.8, 2178.2
	Mean (SD)	371.76 (435.807)	518.95 (457.695)	1898.01 (1462.683)	1827.75 (1505.155)	232.45 (168.584)	542.67 (615.726)
	95% CI of Mean	232.38, 511.14	351.07, 686.84	1193.02, 2603.01	958.69, 2696.80	125.33, 339.57	102.21, 983.14

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.2 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
%Change from baseline to Day 2	n	37	28	17	13	11	10
	Missing, n (%)	6 (14.0)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-79.05	-80.09	-14.39	0.00	-83.45	-82.67
	Q25, Q75	-86.93, -73.86	-85.15, -70.78	-24.39, 15.32	-26.74, 15.16	-87.85, -82.01	-86.53, -72.10
	Min, Max	-92.7, 36.9	-94.5, -53.0	-70.7, 142.1	-75.5, 150.8	-94.5, -69.0	-88.5, -68.2
	Mean (SD)	-73.64 (23.992)	-77.99 (10.356)	3.99 (57.125)	1.94 (54.276)	-83.56 (7.646)	-79.65 (7.671)
	95% CI of Mean	-81.64, -65.63	-82.01, -73.97	-25.38, 33.37	-30.86, 34.74	-88.70, -78.42	-85.14, -74.15

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.2 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Day 3	n	40	31	19	14	12	10
	Missing, n (%)	3 (7.0)	1 (3.1)	1 (5.0)	1 (6.7)	1 (7.7)	1 (9.1)
	BLOQ, n (%)	1 (2.5)	0	0	0	1 (8.3)	0
	Geometric Mean (CV%)	239.21 (108.412)	255.79 (80.963)	1264.54 (148.389)	1339.62 (149.718)	179.86 (72.412)	203.96 (114.662)
	95% CI of Geometric Mean	180.44, 317.13	197.14, 331.89	751.82, 2126.89	716.22, 2505.62	119.05, 271.70	105.90, 392.80
	Median	225.09	284.48	1701.39	1787.35	194.78	162.12
	Q25, Q75	160.25, 311.44	152.00, 372.96	593.71, 2326.80	465.70, 2991.74	144.86, 260.99	117.12, 266.19
	Min, Max	24.5, 4261.7	45.4, 1245.7	118.4, 5986.2	216.5, 7010.7	37.4, 504.7	66.6, 1492.7
	Mean (SD)	401.40 (717.185)	324.08 (247.489)	1907.74 (1536.892)	2121.02 (1915.545)	211.62 (118.495)	329.28 (436.229)
	95% CI of Mean	172.03, 630.77	233.29, 414.86	1166.98, 2648.50	1015.01, 3227.03	136.33, 286.91	17.21, 641.34

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.2 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
%Change from baseline to Day 3	n	37	28	17	13	11	10
	Missing, n (%)	6 (14.0)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-82.53	-86.70	-10.26	-2.68	-87.43	-88.50
	Q25, Q75	-87.92, -73.92	-91.66, -82.07	-31.74, 21.03	-16.32, 34.62	-88.33, -82.91	-92.66, -82.69
	Min, Max	-95.3, 276.4	-95.4, -68.6	-92.3, 132.3	-45.7, 147.0	-95.6, -40.1	-96.8, -80.7
	Mean (SD)	-68.31 (60.548)	-85.76 (6.929)	3.49 (60.293)	13.67 (52.675)	-82.84 (14.699)	-87.98 (5.774)
	95% CI of Mean	-88.50, -48.12	-88.45, -83.07	-27.51, 34.50	-18.16, 45.51	-92.72, -72.96	-92.12, -83.84

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.2 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Day 4	n	40	31	19	14	12	10
	Missing, n (%)	3 (7.0)	1 (3.1)	1 (5.0)	1 (6.7)	1 (7.7)	1 (9.1)
	BLOQ, n (%)	1 (2.5)	0	0	0	1 (8.3)	0
	Geometric Mean (CV%)	149.20 (92.746)	171.23 (84.461)	1431.01 (166.972)	1157.38 (164.622)	126.60 (58.683)	147.51 (126.906)
	95% CI of Geometric Mean	115.97, 191.96	130.82, 224.12	820.48, 2495.81	597.53, 2241.77	89.60, 178.87	73.19, 297.28
	Median	138.92	183.73	1934.39	1575.92	153.97	112.50
	Q25, Q75	98.70, 220.73	98.04, 258.46	1048.67, 3103.98	476.67, 2285.71	77.54, 190.89	88.96, 236.11
	Min, Max	27.1, 954.9	51.8, 895.7	50.1, 5047.3	104.6, 5475.4	48.1, 244.2	32.8, 944.4
	Mean (SD)	205.14 (198.771)	224.49 (186.965)	2105.76 (1408.103)	1835.62 (1576.748)	142.88 (66.157)	240.30 (290.522)
	95% CI of Mean	141.56, 268.71	155.91, 293.08	1427.07, 2784.44	925.23, 2746.01	100.84, 184.92	32.47, 448.14

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.2 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
%Change from baseline to Day 4	n	37	28	17	13	11	10
	Missing, n (%)	6 (14.0)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-88.47	-90.68	6.01	-3.74	-89.34	-91.91
	Q25, Q75	-92.47, -85.54	-93.63, -87.65	-21.98, 54.78	-31.81, 5.79	-92.73, -84.49	-95.85, -88.22
	Min, Max	-96.7, -21.4	-97.8, -80.0	-94.4, 142.7	-58.7, 88.7	-95.1, -71.0	-96.7, -79.5
	Mean (SD)	-83.92 (14.499)	-90.42 (4.783)	12.30 (56.275)	-1.89 (39.858)	-88.26 (6.731)	-91.05 (5.559)
	95% CI of Mean	-88.76, -79.08	-92.28, -88.56	-16.64, 41.23	-25.98, 22.20	-92.79, -83.73	-95.04, -87.07

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.2 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
Day 5	n	40	31	19	14	12	10
	Missing, n (%)	3 (7.0)	1 (3.1)	1 (5.0)	1 (6.7)	1 (7.7)	1 (9.1)
	BLOQ, n (%)	3 (7.5)	1 (3.2)	0	0	2 (16.7)	0
	Geometric Mean (CV%)	125.05 (84.674)	145.61 (89.745)	1023.96 (187.225)	1116.03 (205.768)	122.97 (102.903)	146.39 (100.769)
	95% CI of Geometric Mean	98.84, 158.21	109.83, 193.04	566.84, 1849.69	530.97, 2345.76	71.66, 211.01	80.43, 266.44
	Median	129.60	131.05	1078.00	1685.37	135.47	103.63
	Q25, Q75	80.65, 179.11	88.45, 226.70	266.94, 2440.48	304.94, 2586.21	71.71, 228.31	94.49, 181.51
	Min, Max	18.7, 1269.2	29.1, 761.5	127.0, 6677.6	118.7, 5611.1	20.9, 406.3	55.5, 1008.6
	Mean (SD)	168.73 (195.286)	196.72 (179.067)	1848.28 (1873.778)	1942.39 (1726.625)	161.52 (111.330)	222.68 (288.093)
	95% CI of Mean	106.27, 231.19	131.04, 262.41	945.14, 2751.42	945.46, 2939.32	90.78, 232.26	16.59, 428.78

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.2 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=32)	>19 cig/day (N=43)	10-19 cig/day (N=15)	>19 cig/day (N=20)	10-19 cig/day (N=11)	>19 cig/day (N=13)
%Change from baseline to Day 5	n	37	28	17	13	11	10
	Missing, n (%)	6 (14.0)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-90.82	-92.35	-18.30	15.57	-90.88	-92.62
	Q25, Q75	-93.73, -82.80	-94.27, -88.90	-54.04, 14.87	-27.47, 21.04	-93.47, -85.28	-95.13, -87.62
	Min, Max	-97.5, -57.6	-98.5, -82.8	-91.2, 27.2	-78.5, 71.6	-94.2, -70.7	-97.2, -80.5
	Mean (SD)	-86.78 (10.624)	-91.49 (4.204)	-21.31 (39.244)	-1.10 (45.936)	-88.58 (7.223)	-91.29 (5.002)
	95% CI of Mean	-90.33, -83.23	-93.13, -89.86	-41.50, -1.13	-28.86, 26.67	-93.43, -83.72	-94.87, -87.70

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.2 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=26)	>19 cig/day (N=21)	10-19 cig/day (N=13)	>19 cig/day (N=19)	10-19 cig/day (N=3)	>19 cig/day (N=6)
Baseline	n	19	24	17	12	6	3
	Missing, n (%)	2 (9.5)	2 (7.7)	2 (10.5)	1 (7.7)	0	0
	Geometric Mean (CV%)	1017.05 (107.974)	1989.87 (103.533)	1623.92 (83.234)	1129.73 (138.936)	639.58 (139.410)	2013.31 (33.022)
	95% CI of Geometric Mean	665.77, 1553.68	1387.72, 2853.29	1118.30, 2358.14	584.60, 2183.17	214.94, 1903.05	905.38, 4477.01
	Median	1067.35	2023.67	1539.63	1248.94	584.17	1991.98
	Q25, Q75	729.23, 1944.06	1196.72, 3975.81	1265.69, 2345.39	625.20, 2839.15	310.00, 951.72	1467.46, 2791.80
	Min, Max	93.0, 3131.1	350.3, 9243.9	288.5, 4946.2	160.8, 4350.6	213.5, 3742.5	1467.5, 2791.8
	Mean (SD)	1349.68 (934.611)	2709.21 (2110.829)	2028.40 (1351.559)	1682.09 (1373.345)	1064.33 (1344.682)	2083.74 (666.923)
	95% CI of Mean	899.21, 1800.16	1817.88, 3600.54	1333.48, 2723.31	809.50, 2554.68	-346.83, 2475.50	427.01, 3740.48

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.2 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=26)	>19 cig/day (N=21)	10-19 cig/day (N=13)	>19 cig/day (N=19)	10-19 cig/day (N=3)	>19 cig/day (N=6)
Day 90	n	21	26	19	13	6	3
	BLOQ, n (%)	0	1 (3.8)	0	0	1 (16.7)	0
	Geometric Mean (CV%)	274.68 (208.899)	349.88 (169.621)	1344.44 (111.098)	1055.48 (228.278)	132.66 (111.722)	340.41 (401.516)
	95% CI of Geometric Mean	152.27, 495.50	218.63, 559.91	872.68, 2071.21	466.42, 2388.47	51.58, 341.16	5.17, 22398.28
	Median	332.81	268.95	1514.75	736.98	199.74	296.06
	Q25, Q75	85.27, 583.24	162.44, 674.80	877.78, 2381.73	404.38, 3757.36	74.46, 222.60	67.96, 1960.45
	Min, Max	33.1, 2411.9	25.7, 4007.9	137.7, 5449.5	127.1, 7266.2	27.7, 298.1	68.0, 1960.5
	Mean (SD)	553.38 (644.151)	667.41 (901.749)	1823.71 (1347.498)	2120.20 (2230.812)	170.38 (100.345)	774.82 (1033.098)
	95% CI of Mean	260.16, 846.60	303.18, 1031.64	1174.23, 2473.19	772.13, 3468.27	65.07, 275.69	-1791.54, 3341.19

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.1.2 Descriptive Statistics of S-PMA Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Cigarette Consumption - PP Set**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=26)	>19 cig/day (N=21)	10-19 cig/day (N=13)	>19 cig/day (N=19)	10-19 cig/day (N=3)	>19 cig/day (N=6)
%Change from baseline to Day 90	n	19	24	17	12	6	3
	Missing, n (%)	2 (9.5)	2 (7.7)	2 (10.5)	1 (7.7)	0	0
	Median	-72.17	-88.59	-7.29	0.56	-71.83	-85.14
	Q25, Q75	-90.67, -58.65	-93.62, -31.64	-27.97, 10.18	-53.89, 67.73	-91.08, -65.12	-97.57, 33.60
	Min, Max	-96.8, 21.2	-98.8, 12.1	-68.6, 143.1	-80.6, 180.9	-94.7, -37.9	-97.6, 33.6
	Mean (SD)	-64.63 (32.321)	-65.72 (37.478)	-1.74 (47.189)	15.87 (81.673)	-72.09 (20.539)	-49.70 (72.405)
	95% CI of Mean	-80.22, -49.05	-81.55, -49.89	-26.01, 22.52	-36.03, 67.76	-93.65, -50.53	-229.57, 130.17

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	69		36		36	
	Missing, n (%)	11 (13.8)		5 (12.2)		3 (7.7)	
	Geometric Mean (CV%)	1547.31 (105.343)		1628.13 (113.478)		1589.61 (106.187)	
	95% CI of Geometric Mean	1257.28, 1904.24		1196.77, 2214.96		1184.70, 2132.90	
	Median	1819.14		1528.61		1726.54	
	Q25, Q75	1052.63, 2691.81		978.05, 3637.09		1030.09, 2873.78	
	Min, Max	93.0, 9243.9		160.8, 8363.3		213.5, 8015.0	
	Mean (SD)	2104.26 (1622.262)		2287.76 (1820.176)		2197.28 (1807.373)	
	95% CI of Mean	1714.55, 2493.98		1671.89, 2903.62		1585.74, 2808.81	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	1 (1.3)		0		0	
	Geometric Mean (CV%)	706.87 (116.901)		1549.44 (137.962)		667.59 (146.879)	
	95% CI of Geometric Mean	570.94, 875.15		1108.74, 2165.31		466.92, 954.50	
	Median	802.61	-54.45	1664.23	0.82	800.35	-59.39
	Q25, Q75	361.02, 1256.87	-65.15, -40.00	883.04, 3555.93	-19.52, 28.70	290.74, 1563.49	-71.68, -37.36
	Min, Max	47.2, 6220.9	-83.2, 129.5	91.3, 8474.9	-62.2, 116.2	58.3, 4532.2	-92.8, 0.0
	Mean (SD)	1046.18 (1048.865)	-48.73 (31.067)	2333.63 (1928.504)	7.74 (40.575)	1064.74 (993.978)	-50.94 (27.510)
	95% CI of Mean	804.85, 1287.51	-56.20, -41.27	1708.47, 2958.78	-5.99, 21.47	733.33, 1396.16	-60.26, -41.63

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	1 (1.3)		0		1 (2.7)	
	Geometric Mean (CV%)	303.18 (99.934)		1416.28 (149.693)		298.10 (183.905)	
	95% CI of Geometric Mean	250.34, 367.16		996.53, 2012.83		198.76, 447.07	
	Median	280.33	-79.72	1954.02	-3.15	275.00	-83.01
	Q25, Q75	189.47, 509.11	-86.39, -73.86	871.82, 3104.33	-23.13, 15.24	142.86, 577.71	-86.95, -72.13
	Min, Max	32.2, 2512.8	-94.5, 36.9	117.8, 7732.1	-75.5, 150.8	25.9, 3261.5	-98.0, 0.0
	Mean (SD)	430.85 (439.915)	-76.16 (18.994)	2183.68 (1782.855)	3.35 (50.952)	616.66 (844.139)	-71.53 (30.049)
	95% CI of Mean	329.63, 532.07	-80.73, -71.59	1605.74, 2761.62	-13.89, 20.60	335.21, 898.12	-81.71, -61.36

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	1 (1.3)		0		1 (2.7)	
	Geometric Mean (CV%)	244.48 (93.715)		1518.87 (149.055)		244.80 (166.781)	
	95% CI of Geometric Mean	203.66, 293.49		1069.66, 2156.73		166.65, 359.61	
	Median	235.66	-85.34	1874.49	-3.15	183.33	-87.34
	Q25, Q75	160.00, 369.17	-91.01, -78.33	615.78, 2991.74	-21.63, 33.59	117.12, 316.09	-90.24, -80.50
	Min, Max	24.5, 4261.7	-95.4, 276.4	118.4, 10059.2	-92.3, 147.0	37.4, 3261.5	-97.6, 0.0
	Mean (SD)	361.22 (546.956)	-76.66 (45.203)	2385.46 (2132.413)	10.19 (53.163)	533.01 (829.239)	-74.35 (31.769)
	95% CI of Mean	235.37, 487.06	-87.52, -65.79	1694.21, 3076.71	-7.81, 28.18	256.52, 809.49	-85.10, -63.59

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	1 (1.3)		0		1 (2.7)	
	Geometric Mean (CV%)	157.09 (86.872)		1490.69 (157.673)		190.53 (182.240)	
	95% CI of Geometric Mean	132.19, 186.68		1037.68, 2141.47		127.28, 285.19	
	Median	142.23	-90.08	1960.78	-1.87	132.46	-90.44
	Q25, Q75	98.04, 248.90	-93.12, -86.85	1019.87, 3001.19	-29.64, 38.24	88.96, 244.19	-93.48, -83.24
	Min, Max	27.1, 954.9	-97.8, -21.4	50.1, 8539.6	-94.4, 142.7	32.8, 3261.5	-98.2, 0.0
	Mean (SD)	210.25 (188.719)	-87.13 (11.546)	2254.74 (1749.704)	6.39 (48.945)	475.70 (829.740)	-77.35 (32.028)
	95% CI of Mean	166.82, 253.67	-89.91, -84.36	1687.55, 2821.93	-10.18, 22.95	199.05, 752.35	-88.19, -66.50

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	4 (5.3)		0		2 (5.4)	
	Geometric Mean (CV%)	133.21 (84.715)		1287.28 (194.203)		179.45 (194.428)	
	95% CI of Geometric Mean	112.47, 157.78		858.39, 1930.46		118.25, 272.31	
	Median	130.87	-91.33	1676.47	1.09	123.70	-90.68
	Q25, Q75	86.56, 209.76	-94.16, -87.63	554.41, 4041.24	-36.56, 17.08	89.12, 240.19	-94.14, -83.47
	Min, Max	18.7, 1269.2	-98.5, -57.6	118.7, 9019.3	-91.2, 184.6	20.9, 3261.5	-98.5, 0.0
	Mean (SD)	178.82 (183.499)	-89.13 (8.592)	2289.10 (2134.670)	-5.09 (51.072)	469.34 (832.706)	-77.92 (32.224)
	95% CI of Mean	136.60, 221.04	-91.20, -87.06	1597.11, 2981.08	-22.38, 12.19	191.70, 746.99	-88.83, -67.01

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	0		0		1 (2.7)	
	Geometric Mean (CV%)	428.73 (163.038)		1585.04 (149.748)		516.84 (228.241)	
	95% CI of Geometric Mean	329.90, 557.17		1115.19, 2252.85		329.37, 811.03	
	Median	614.05	-68.29	2339.54	2.00	603.83	-66.44
	Q25, Q75	170.11, 942.52	-89.07, -46.06	851.85, 3616.67	-14.73, 23.70	190.78, 1516.13	-78.83, -34.89
	Min, Max	43.7, 3990.1	-99.1, 251.8	77.4, 7042.3	-86.2, 208.5	35.9, 3307.4	-96.9, 125.4
	Mean (SD)	746.36 (820.572)	-53.35 (58.722)	2389.04 (1781.929)	13.79 (55.513)	1024.89 (1033.879)	-52.93 (43.705)
	95% CI of Mean	557.56, 935.16	-67.46, -39.24	1811.40, 2966.68	-5.00, 32.58	680.17, 1369.61	-67.72, -38.14

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	0		0		1 (2.7)	
	Geometric Mean (CV%)	444.79 (179.373)		1310.90 (141.578)		617.46 (230.038)	
	95% CI of Geometric Mean	337.50, 586.19		933.06, 1841.75		392.85, 970.49	
	Median	626.19	-71.36	1373.83	-13.25	832.26	-57.05
	Q25, Q75	152.38, 1093.46	-85.52, -33.95	490.97, 2676.80	-38.42, 17.23	271.15, 1765.60	-78.22, -17.56
	Min, Max	30.3, 4843.3	-98.6, 371.1	127.1, 8145.4	-90.2, 186.7	18.7, 3909.1	-98.1, 166.4
	Mean (SD)	820.33 (924.057)	-47.44 (74.306)	2044.63 (1859.079)	-1.69 (53.620)	1131.41 (1018.954)	-43.22 (53.188)
	95% CI of Mean	607.72, 1032.94	-65.29, -29.58	1441.98, 2647.28	-19.84, 16.46	791.67, 1471.15	-61.23, -25.22

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	2 (2.7)		0		1 (2.7)	
	Geometric Mean (CV%)	416.92 (218.503)		1454.60 (154.067)		571.89 (217.514)	
	95% CI of Geometric Mean	307.42, 565.42		1017.41, 2079.64		368.11, 888.47	
	Median	441.39	-68.14	1578.57	-2.81	832.26	-63.19
	Q25, Q75	162.44, 1098.40	-91.57, -26.33	686.11, 3757.36	-25.99, 33.13	296.06, 1560.75	-81.33, -30.17
	Min, Max	12.7, 10398.3	-99.3, 306.9	127.1, 7722.6	-80.6, 180.9	27.7, 5409.6	-97.6, 33.6
	Mean (SD)	906.33 (1458.821)	-50.10 (65.414)	2330.79 (2040.635)	5.92 (56.728)	1102.23 (1183.636)	-51.09 (35.234)
	95% CI of Mean	570.68, 1241.98	-65.82, -34.38	1669.29, 2992.29	-13.28, 25.12	707.58, 1496.87	-63.01, -39.16

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	71	36	36
	Missing, n (%)	9 (11.3)	5 (12.2)	3 (7.7)
	Geometric Mean (CV%)	2572.51 (94.816)	2602.17 (116.144)	2601.34 (109.389)
	95% CI of Geometric Mean	2128.31, 3109.43	1903.45, 3557.36	1926.84, 3511.95
	Median	2691.16	2844.14	3275.77
	Q25, Q75	1637.94, 4482.08	1568.97, 5457.71	1694.75, 4682.58
	Min, Max	230.2, 10411.1	308.5, 13471.1	318.7, 11475.1
	Mean (SD)	3358.76 (2341.599)	3651.57 (2854.572)	3536.16 (2557.005)
	95% CI of Mean	2804.50, 3913.01	2685.72, 4617.43	2670.98, 4401.33

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 1	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n (%)	1 (1.3)	0	0
	Geometric Mean (CV%)	1153.88 (105.487)	2493.45 (138.125)	1110.99 (139.943)
	95% CI of Geometric Mean	945.67, 1407.93	1783.81, 3485.38	785.06, 1572.23
	Median	1215.55	3098.94	1157.76
	Q25, Q75	713.70, 2118.49	1600.20, 5689.62	679.91, 2387.84
	Min, Max	61.4, 5654.7	224.1, 12288.5	76.7, 6589.8
	Mean (SD)	1574.44 (1203.414)	3708.75 (2868.603)	1709.25 (1494.814)
	95% CI of Mean	1297.56, 1851.33	2778.85, 4638.64	1210.85, 2207.65

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 2	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n (%)	1 (1.3)	0	1 (2.7)
	Geometric Mean (CV%)	496.24 (92.757)	2311.80 (147.564)	483.28 (172.375)
	95% CI of Geometric Mean	413.96, 594.87	1631.46, 3275.84	326.70, 714.91
	Median	518.83	2676.12	371.97
	Q25, Q75	307.94, 798.81	969.68, 5110.70	244.55, 914.88
	Min, Max	63.1, 3560.3	172.5, 11852.4	46.4, 6589.8
	Mean (SD)	666.83 (599.637)	3522.84 (2767.269)	985.97 (1411.260)
	95% CI of Mean	528.86, 804.80	2625.79, 4419.89	515.42, 1456.51

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 3	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n (%)	1 (1.3)	0	1 (2.7)
	Geometric Mean (CV%)	399.42 (85.713)	2444.42 (144.525)	389.47 (163.059)
	95% CI of Geometric Mean	336.71, 473.80	1732.49, 3448.92	266.41, 569.37
	Median	400.85	4056.66	315.24
	Q25, Q75	286.13, 590.24	1065.29, 4978.26	176.26, 595.73
	Min, Max	54.2, 5041.0	165.8, 11699.4	81.2, 6589.8
	Mean (SD)	544.30 (660.781)	3688.58 (2843.870)	855.39 (1416.504)
	95% CI of Mean	392.26, 696.34	2766.70, 4610.46	383.10, 1327.68

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 4	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n (%)	1 (1.3)	0	1 (2.7)
	Geometric Mean (CV%)	257.95 (77.952)	2392.87 (152.195)	305.29 (177.372)
	95% CI of Geometric Mean	220.12, 302.26	1677.92, 3412.44	205.13, 454.36
	Median	243.98	3289.84	226.09
	Q25, Q75	171.14, 397.82	1798.48, 5519.57	132.81, 361.46
	Min, Max	50.6, 1391.4	86.2, 13158.3	71.6, 6589.8
	Mean (SD)	329.54 (266.808)	3598.04 (2744.778)	777.99 (1435.746)
	95% CI of Mean	268.15, 390.93	2708.28, 4487.80	299.29, 1256.70

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 5	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n (%)	4 (5.3)	0	2 (5.4)
	Geometric Mean (CV%)	225.72 (77.179)	2122.56 (187.148)	304.35 (186.900)
	95% CI of Geometric Mean	192.86, 264.17	1426.17, 3158.99	202.24, 458.02
	Median	225.22	2521.88	219.84
	Q25, Q75	153.06, 332.67	848.24, 5785.20	166.95, 457.93
	Min, Max	28.1, 1918.0	161.1, 14835.1	31.4, 6589.8
	Mean (SD)	287.22 (258.080)	3667.65 (3267.326)	781.86 (1434.612)
	95% CI of Mean	227.84, 346.60	2608.50, 4726.80	303.53, 1260.19

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n (%)	0	0	1 (2.7)
	Geometric Mean (CV%)	694.51 (165.883)	2511.73 (141.100)	850.53 (226.239)
	95% CI of Geometric Mean	533.06, 904.86	1789.02, 3526.40	543.01, 1332.20
	Median	904.73	3802.05	1096.56
	Q25, Q75	210.12, 1608.98	991.94, 5492.27	282.08, 2695.00
	Min, Max	37.9, 5209.5	198.8, 11181.5	81.2, 6589.8
	Mean (SD)	1200.88 (1205.800)	3702.50 (2634.649)	1703.19 (1784.379)
	95% CI of Mean	923.45, 1478.32	2848.45, 4556.56	1108.25, 2298.14

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n (%)	0	0	1 (2.7)
	Geometric Mean (CV%)	712.48 (169.485)	2135.96 (150.664)	1045.58 (244.587)
	95% CI of Geometric Mean	545.13, 931.20	1500.91, 3039.71	656.89, 1664.24
	Median	928.73	2705.98	1629.92
	Q25, Q75	266.88, 1714.90	913.50, 4912.94	406.89, 2879.20
	Min, Max	55.5, 6763.5	76.5, 10012.4	58.3, 7653.9
	Mean (SD)	1262.91 (1342.864)	3269.29 (2612.989)	2041.05 (2030.404)
	95% CI of Mean	953.94, 1571.88	2422.25, 4116.33	1364.08, 2718.03

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.2 Descriptive Statistics of S-PMA in 24-hour Urine Collection - FAS****Parameter (units): S-PMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n (%)	2 (2.7)	0	1 (2.7)
	Geometric Mean (CV%)	696.06 (205.077)	2299.80 (140.923)	933.48 (216.235)
	95% CI of Geometric Mean	517.96, 935.38	1638.49, 3228.01	601.59, 1448.45
	Median	778.36	3343.38	1055.65
	Q25, Q75	241.52, 1763.36	856.60, 4791.60	406.61, 2851.58
	Min, Max	28.7, 7850.9	204.7, 10449.7	73.1, 6589.8
	Mean (SD)	1355.20 (1558.037)	3467.43 (2681.864)	1759.14 (1681.929)
	95% CI of Mean	996.72, 1713.68	2598.06, 4336.79	1198.35, 2319.93

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		30		21	
	Missing, n (%)	10 (13.3)		5 (14.3)		3 (12.5)	
	Geometric Mean (CV%)	1510.14 (108.680)		1433.17 (107.941)		1488.78 (102.283)	
	95% CI of Geometric Mean	1213.34, 1879.53		1032.20, 1989.89		1012.87, 2188.30	
	Median	1776.79		1486.69		1624.50	
	Q25, Q75	1045.51, 2691.81		902.14, 3178.29		951.72, 2256.10	
	Min, Max	93.0, 9243.9		160.8, 4946.2		213.5, 8015.0	
	Mean (SD)	2088.90 (1665.760)		1946.08 (1392.191)		2020.19 (1712.810)	
	95% CI of Mean	1676.14, 2501.66		1426.22, 2465.94		1240.53, 2799.86	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	1 (1.4)		0		0	
	Geometric Mean (CV%)	694.93 (119.599)		1344.34 (134.554)		602.09 (136.564)	
	95% CI of Geometric Mean	555.99, 868.59		937.49, 1927.76		382.04, 948.89	
	Median	802.61	-52.46	1472.30	3.85	704.52	-53.20
	Q25, Q75	357.66, 1256.87	-65.15, -40.00	667.14, 3290.16	-26.63, 28.85	290.74, 1174.19	-71.96, -43.45
	Min, Max	47.2, 6220.9	-83.2, 129.5	91.3, 6110.2	-62.2, 101.1	58.3, 4532.2	-92.8, -12.2
	Mean (SD)	1041.71 (1065.440)	-48.31 (31.687)	1994.46 (1591.973)	6.02 (39.252)	935.97 (964.772)	-55.52 (20.790)
	95% CI of Mean	789.52, 1293.90	-56.17, -40.45	1429.96, 2558.95	-8.65, 20.68	508.21, 1363.73	-64.98, -46.05

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	1 (1.4)		0		1 (4.5)	
	Geometric Mean (CV%)	304.41 (102.054)		1224.38 (147.838)		241.86 (121.679)	
	95% CI of Geometric Mean	249.23, 371.80		835.90, 1793.39		158.50, 369.07	
	Median	292.52	-79.49	1347.42	-2.77	243.33	-83.45
	Q25, Q75	183.39, 509.11	-86.27, -70.91	564.49, 2956.52	-26.74, 15.32	142.86, 409.35	-86.53, -72.82
	Min, Max	32.2, 2512.8	-94.5, 36.9	117.8, 5703.9	-75.5, 150.8	25.9, 2178.2	-94.5, -68.2
	Mean (SD)	436.03 (448.332)	-75.51 (19.333)	1868.20 (1457.750)	3.10 (54.959)	373.46 (449.848)	-81.70 (7.728)
	95% CI of Mean	329.90, 542.15	-80.31, -70.72	1351.30, 2385.10	-17.42, 23.63	174.01, 572.92	-85.22, -78.17

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	1 (1.4)		0		1 (4.5)	
	Geometric Mean (CV%)	246.31 (95.700)		1295.86 (145.108)		190.44 (89.125)	
	95% CI of Geometric Mean	203.51, 298.11		888.43, 1890.13		135.68, 267.29	
	Median	240.52	-85.01	1701.39	-3.97	174.79	-87.43
	Q25, Q75	160.00, 369.17	-89.69, -77.85	593.71, 2886.79	-28.64, 34.62	127.93, 266.19	-89.74, -82.91
	Min, Max	24.5, 4261.7	-95.4, 276.4	118.4, 7010.7	-92.3, 147.0	37.4, 1492.7	-96.8, -40.1
	Mean (SD)	367.64 (560.635)	-75.83 (46.457)	1998.22 (1682.487)	7.91 (56.392)	265.10 (304.148)	-85.29 (11.399)
	95% CI of Mean	234.93, 500.34	-87.34, -64.31	1401.63, 2594.81	-13.16, 28.97	130.25, 399.96	-90.48, -80.10

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	1 (1.4)		0		1 (4.5)	
	Geometric Mean (CV%)	158.45 (88.790)		1307.80 (162.607)		135.71 (87.885)	
	95% CI of Geometric Mean	132.28, 189.79		873.82, 1957.29		97.03, 189.80	
	Median	142.73	-90.00	1790.54	-1.87	120.55	-91.62
	Q25, Q75	98.04, 248.90	-92.96, -86.67	1019.87, 2926.83	-30.90, 50.62	86.36, 196.70	-92.78, -88.22
	Min, Max	27.1, 954.9	-97.8, -21.4	50.1, 5475.4	-94.4, 142.7	32.8, 944.4	-96.7, -71.0
	Mean (SD)	213.59 (192.581)	-86.72 (11.765)	1991.15 (1464.129)	6.15 (49.555)	187.16 (202.313)	-89.59 (6.213)
	95% CI of Mean	168.00, 259.18	-89.64, -83.80	1471.99, 2510.32	-12.36, 24.66	97.46, 276.87	-92.43, -86.76

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	4 (5.6)		0		2 (9.1)	
	Geometric Mean (CV%)	133.64 (86.656)		1062.05 (189.124)		133.11 (99.339)	
	95% CI of Geometric Mean	111.94, 159.55		685.84, 1644.62		92.18, 192.21	
	Median	131.05	-91.16	1557.46	-0.64	123.18	-91.74
	Q25, Q75	81.06, 209.76	-93.96, -86.95	304.94, 2440.48	-54.04, 17.40	89.12, 216.43	-93.56, -87.62
	Min, Max	18.7, 1269.2	-98.5, -57.6	118.7, 6677.6	-91.2, 71.6	20.9, 1008.6	-97.2, -70.7
	Mean (SD)	180.95 (187.577)	-88.81 (8.745)	1888.20 (1785.587)	-12.55 (42.740)	189.32 (207.447)	-89.87 (6.267)
	95% CI of Mean	136.55, 225.36	-90.98, -86.64	1255.06, 2521.35	-28.52, 3.41	97.34, 281.30	-92.73, -87.01

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=32)		mCC (N=34)		SA (N=8)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		29		8	
	Missing, n (%)	4 (12.5)		5 (14.7)		0	
	Geometric Mean (CV%)	1291.23 (132.957)		1445.75 (110.347)		1737.28 (132.844)	
	95% CI of Geometric Mean	873.15, 1909.50		1029.59, 2030.12		747.69, 4036.58	
	Median	1278.87		1458.80		2037.07	
	Q25, Q75	733.41, 2792.42		902.14, 3178.29		880.72, 3267.13	
	Min, Max	93.0, 9243.9		160.8, 4946.2		310.0, 8015.0	
	Mean (SD)	1974.45 (1928.710)		1974.06 (1407.396)		2586.86 (2463.068)	
	95% CI of Mean	1226.57, 2722.33		1438.71, 2509.41		527.68, 4646.04	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=32)		mCC (N=34)		SA (N=8)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	28	32	29	8	8
	Missing, n (%)	1 (3.1)	4 (12.5)	2 (5.9)	5 (14.7)	0	0
	BLOQ, n (%)	0		0		1 (12.5)	
	Geometric Mean (CV%)	331.34 (192.802)		1402.80 (155.739)		221.60 (250.642)	
	95% CI of Geometric Mean	209.83, 523.22		940.26, 2092.85		68.23, 719.74	
	Median	566.97	-73.35	2161.42	4.91	165.52	-82.43
	Q25, Q75	122.16, 822.41	-90.64, -46.17	702.41, 3354.25	-14.02, 24.27	84.34, 615.40	-96.08, -64.39
	Min, Max	43.7, 3691.9	-99.1, 197.4	77.4, 5188.9	-86.2, 208.5	35.9, 2765.2	-96.9, -57.7
	Mean (SD)	645.23 (786.430)	-55.33 (60.776)	2130.86 (1521.784)	15.56 (60.720)	566.46 (929.666)	-80.04 (16.362)
	95% CI of Mean	356.76, 933.70	-78.90, -31.76	1582.19, 2679.53	-7.54, 38.66	-210.77, 1343.68	-93.73, -66.36

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=36)		mCC (N=34)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	33		30		7	
	Missing, n (%)	3 (8.3)		4 (11.8)		0	
	Geometric Mean (CV%)	1394.36 (117.565)		1448.78 (107.603)		1008.56 (150.027)	
	95% CI of Geometric Mean	1002.08, 1940.21		1044.20, 2010.13		369.48, 2753.00	
	Median	1234.38		1488.19		951.72	
	Q25, Q75	755.63, 2663.27		902.14, 3178.29		310.00, 2791.80	
	Min, Max	93.0, 9243.9		160.8, 4946.2		213.5, 3742.5	
	Mean (SD)	2048.70 (1948.985)		1959.58 (1385.190)		1544.45 (1340.016)	
	95% CI of Mean	1357.62, 2739.79		1442.33, 2476.82		305.14, 2783.77	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=36)		mCC (N=34)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	36	33	32	30	7	7
	Missing, n (%)	0	3 (8.3)	2 (5.9)	4 (11.8)	0	0
	BLOQ, n (%)	0		0		1 (14.3)	
	Geometric Mean (CV%)	318.41 (167.248)		1130.80 (141.620)		121.72 (182.424)	
	95% CI of Geometric Mean	215.40, 470.68		774.69, 1650.62		39.73, 372.84	
	Median	273.97	-77.64	1318.08	-19.25	237.95	-88.05
	Q25, Q75	138.70, 791.46	-90.01, -56.40	473.82, 2341.13	-43.79, 54.28	47.01, 271.15	-93.98, -68.34
	Min, Max	30.3, 3810.7	-98.6, 264.5	127.1, 8145.4	-90.2, 186.7	18.7, 509.3	-98.1, -46.5
	Mean (SD)	579.59 (704.915)	-58.70 (65.720)	1779.08 (1725.109)	-0.40 (58.640)	199.14 (174.677)	-80.81 (18.296)
	95% CI of Mean	341.08, 818.10	-82.00, -35.39	1157.11, 2401.06	-22.30, 21.51	37.58, 360.69	-97.74, -63.89

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=41)		mCC (N=31)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		29		7	
	Missing, n (%)	4 (9.8)		2 (6.5)		0	
	Geometric Mean (CV%)	1422.17 (119.397)		1397.51 (106.313)		1008.56 (150.027)	
	95% CI of Geometric Mean	1039.07, 1946.50		1003.91, 1945.42		369.48, 2753.00	
	Median	1323.37		1458.80		951.72	
	Q25, Q75	758.62, 2835.20		902.14, 2500.00		310.00, 2791.80	
	Min, Max	93.0, 9243.9		160.8, 4946.2		213.5, 3742.5	
	Mean (SD)	2070.10 (1872.852)		1885.10 (1347.191)		1544.45 (1340.016)	
	95% CI of Mean	1445.66, 2694.55		1372.65, 2397.55		305.14, 2783.77	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population****Parameter (units): S-PMA (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=41)		mCC (N=31)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	41	37	31	29	7	7
	Missing, n (%)	0	4 (9.8)	0	2 (6.5)	0	0
	BLOQ, n (%)	1 (2.4)		0		1 (14.3)	
	Geometric Mean (CV%)	308.52 (195.931)		1175.01 (150.596)		125.58 (111.600)	
	95% CI of Geometric Mean	207.56, 458.59		788.30, 1751.42		54.66, 288.52	
	Median	274.19	-81.14	1362.16	-6.58	196.87	-85.14
	Q25, Q75	129.85, 636.36	-93.46, -37.57	484.90, 2655.28	-28.49, 33.45	67.96, 296.06	-94.74, -68.68
	Min, Max	25.7, 4007.9	-98.8, 21.2	127.1, 7266.2	-80.6, 180.9	27.7, 298.1	-97.6, -65.1
	Mean (SD)	632.88 (834.200)	-64.23 (36.340)	1885.40 (1728.731)	5.54 (63.015)	166.24 (110.893)	-82.47 (12.954)
	95% CI of Mean	369.57, 896.19	-76.35, -52.11	1251.29, 2519.51	-18.43, 29.52	63.68, 268.81	-94.46, -70.49

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	67	30	21
	Missing, n (%)	8 (10.7)	5 (14.3)	3 (12.5)
	Geometric Mean (CV%)	2509.60 (97.261)	2272.12 (111.126)	2387.22 (105.035)
	95% CI of Geometric Mean	2056.68, 3062.24	1625.56, 3175.85	1612.26, 3534.68
	Median	2616.89	2711.77	3141.39
	Q25, Q75	1626.01, 4482.08	1499.78, 4741.20	1650.05, 3917.16
	Min, Max	230.2, 10411.1	308.5, 6707.6	318.7, 8650.3
	Mean (SD)	3320.29 (2395.195)	3071.19 (2009.484)	3173.02 (2202.545)
	95% CI of Mean	2736.05, 3904.53	2320.83, 3821.54	2170.43, 4175.61

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	1 (1.4)	0	0
	Geometric Mean (CV%)	1136.98 (108.284)	2165.27 (136.353)	972.52 (132.196)
	95% CI of Geometric Mean	923.01, 1400.56	1505.47, 3114.24	622.74, 1518.74
	Median	1153.75	2735.68	988.54
	Q25, Q75	688.90, 2118.49	1024.99, 5610.46	679.91, 2188.27
	Min, Max	61.4, 5654.7	224.1, 8360.3	76.7, 4693.4
	Mean (SD)	1570.84 (1226.997)	3192.92 (2371.520)	1436.36 (1213.066)
	95% CI of Mean	1280.41, 1861.27	2352.01, 4033.83	898.52, 1974.21

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	1 (1.4)	0	1 (4.5)
	Geometric Mean (CV%)	499.81 (95.348)	2001.45 (147.487)	379.88 (111.694)
	95% CI of Geometric Mean	413.18, 604.60	1367.15, 2930.03	254.89, 566.15
	Median	539.34	2534.95	367.72
	Q25, Q75	307.94, 798.81	900.69, 4624.00	195.69, 671.93
	Min, Max	63.1, 3560.3	172.5, 8233.7	46.4, 2301.2
	Mean (SD)	677.68 (612.725)	3047.05 (2321.098)	548.52 (519.242)
	95% CI of Mean	532.65, 822.71	2224.02, 3870.08	318.30, 778.74

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	1 (1.4)	0	1 (4.5)
	Geometric Mean (CV%)	402.95 (88.056)	2095.72 (144.027)	294.07 (81.062)
	95% CI of Geometric Mean	336.79, 482.10	1439.24, 3051.62	214.58, 402.99
	Median	416.02	3179.08	327.67
	Q25, Q75	290.86, 601.55	848.24, 4467.60	163.61, 435.77
	Min, Max	54.2, 5041.0	165.8, 10156.7	84.8, 1462.9
	Mean (SD)	554.48 (677.191)	3167.52 (2410.120)	374.52 (298.918)
	95% CI of Mean	394.19, 714.78	2312.93, 4022.12	241.99, 507.06

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	1 (1.4)	0	1 (4.5)
	Geometric Mean (CV%)	261.33 (79.467)	2085.41 (154.536)	212.78 (75.027)
	95% CI of Geometric Mean	221.44, 308.40	1409.54, 3085.34	158.21, 286.16
	Median	243.98	2496.96	215.28
	Q25, Q75	171.14, 424.72	968.86, 4896.36	129.92, 322.67
	Min, Max	50.6, 1391.4	86.2, 7708.9	74.0, 1035.0
	Mean (SD)	335.66 (272.318)	3129.41 (2209.487)	270.19 (229.588)
	95% CI of Mean	271.20, 400.12	2345.95, 3912.86	168.39, 371.99

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n (%)	4 (5.6)	0	2 (9.1)
	Geometric Mean (CV%)	226.72 (78.949)	1740.95 (180.388)	221.98 (89.625)
	95% CI of Geometric Mean	192.28, 267.33	1136.29, 2667.37	157.92, 312.01
	Median	225.22	2436.79	220.96
	Q25, Q75	153.06, 332.67	427.52, 5015.40	130.46, 300.72
	Min, Max	28.1, 1918.0	161.1, 7658.7	31.4, 1072.0
	Mean (SD)	290.66 (264.015)	2961.66 (2463.585)	290.23 (238.344)
	95% CI of Mean	228.16, 353.15	2088.10, 3835.21	184.55, 395.91

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=32)	mCC (N=34)	SA (N=8)
		Value	Value	Value
Baseline	n	29	29	8
	Missing, n (%)	3 (9.4)	5 (14.7)	0
	Geometric Mean (CV%)	2078.91 (108.394)	2370.46 (110.394)	2668.90 (118.137)
	95% CI of Geometric Mean	1486.68, 2907.05	1687.95, 3328.92	1221.70, 5830.43
	Median	2287.43	2808.69	3529.28
	Q25, Q75	1034.00, 4014.08	1503.88, 4741.20	1474.63, 4962.08
	Min, Max	230.2, 10411.1	308.5, 6707.6	500.2, 8650.3
	Mean (SD)	2861.91 (2260.165)	3167.54 (1991.755)	3635.31 (2658.720)
	95% CI of Mean	2002.19, 3721.64	2409.91, 3925.17	1412.56, 5858.06

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=32)	mCC (N=34)	SA (N=8)
		Value	Value	Value
Day 30	n	31	32	8
	Missing, n (%)	1 (3.1)	2 (5.9)	0
	BLOQ, n (%)	0	0	1 (12.5)
	Geometric Mean (CV%)	522.39 (195.978)	2342.97 (142.576)	337.48 (187.607)
	95% CI of Geometric Mean	329.56, 828.04	1602.64, 3425.28	120.87, 942.28
	Median	655.22	3800.51	233.80
	Q25, Q75	204.25, 1392.42	1054.80, 5424.94	115.97, 945.01
	Min, Max	37.9, 5209.5	198.8, 6777.5	105.2, 2695.0
	Mean (SD)	1027.27 (1210.366)	3410.54 (2208.643)	673.72 (895.930)
	95% CI of Mean	583.30, 1471.24	2614.24, 4206.85	-75.30, 1422.74

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=36)	mCC (N=34)	SA (N=7)
		Value	Value	Value
Baseline	n	34	30	7
	Missing, n (%)	2 (5.6)	4 (11.8)	0
	Geometric Mean (CV%)	2342.34 (96.549)	2359.91 (107.696)	1627.07 (157.967)
	95% CI of Geometric Mean	1764.69, 3109.07	1700.55, 3274.92	578.21, 4578.56
	Median	2179.44	2726.79	1888.23
	Q25, Q75	1527.97, 4520.10	1503.88, 4741.20	500.22, 4262.16
	Min, Max	230.2, 10411.1	308.5, 6707.6	318.7, 5662.0
	Mean (SD)	3155.90 (2557.527)	3131.07 (1967.279)	2515.64 (2094.131)
	95% CI of Mean	2263.53, 4048.27	2396.48, 3865.67	578.88, 4452.39

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=36)	mCC (N=34)	SA (N=7)
		Value	Value	Value
Day 60	n	36	32	7
	Missing, n (%)	0	2 (5.9)	0
	BLOQ, n (%)	0	0	1 (14.3)
	Geometric Mean (CV%)	507.07 (142.825)	1904.35 (154.002)	201.13 (166.277)
	95% CI of Geometric Mean	354.91, 724.46	1279.74, 2833.80	69.34, 583.36
	Median	489.27	2510.87	217.50
	Q25, Q75	206.52, 1289.78	841.94, 4604.59	64.99, 500.54
	Min, Max	55.5, 4550.5	76.5, 8675.5	60.7, 1130.7
	Mean (SD)	832.93 (878.413)	2921.61 (2306.471)	346.23 (385.582)
	95% CI of Mean	535.72, 1130.15	2090.03, 3753.18	-10.37, 702.84

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=41)	mCC (N=31)	SA (N=7)
		Value	Value	Value
Baseline	n	39	29	7
	Missing, n (%)	2 (4.9)	2 (6.5)	0
	Geometric Mean (CV%)	2318.48 (101.846)	2286.44 (107.337)	1627.07 (157.967)
	95% CI of Geometric Mean	1763.78, 3047.64	1638.83, 3189.97	578.21, 4578.56
	Median	2292.00	2644.89	1888.23
	Q25, Q75	1527.97, 4520.10	1503.88, 4407.76	500.22, 4262.16
	Min, Max	230.2, 10411.1	308.5, 6707.6	318.7, 5662.0
	Mean (SD)	3141.20 (2457.041)	3035.44 (1929.822)	2515.64 (2094.131)
	95% CI of Mean	2344.71, 3937.69	2301.37, 3769.51	578.88, 4452.39

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.4.3 Descriptive Statistics of S-PMA in 24-hour Urine Collection - Compliant Population**

Parameter (units): S-PMA (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=41)	mCC (N=31)	SA (N=7)
		Value	Value	Value
Day 90	n	41	31	7
	BLOQ, n (%)	1 (2.4)	0	1 (14.3)
	Geometric Mean (CV%)	507.93 (200.203)	1967.70 (143.000)	207.67 (119.706)
	95% CI of Geometric Mean	340.25, 758.22	1336.17, 2897.71	86.82, 496.72
	Median	478.56	2383.92	211.12
	Q25, Q75	188.22, 1520.64	777.97, 4476.13	85.72, 609.15
	Min, Max	47.1, 5350.4	204.7, 8700.6	75.6, 703.9
	Mean (SD)	1058.94 (1340.756)	3012.07 (2419.898)	298.82 (260.566)
	95% CI of Mean	635.75, 1482.14	2124.44, 3899.70	57.83, 539.81

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		30		21	
	Missing, n (%)	8 (10.7)		5 (14.3)		3 (12.5)	
	BLOQ, n (%)	1 (1.5)		0		0	
	Geometric Mean (CV%)	150.01 (115.699)		147.90 (115.044)		142.18 (112.752)	
	95% CI of Geometric Mean	119.80, 187.83		104.97, 208.39		94.14, 214.73	
	Median	187.11		136.01		118.29	
	Q25, Q75	108.94, 241.58		93.73, 313.23		79.32, 242.70	
	Min, Max	5.0, 643.9		15.3, 1154.7		35.3, 979.6	
	Mean (SD)	201.30 (138.980)		216.97 (218.738)		217.52 (237.431)	
	95% CI of Mean	167.39, 235.20		135.29, 298.65		109.44, 325.60	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	93.92 (106.580)		130.23 (112.157)		97.33 (110.314)	
	95% CI of Geometric Mean	76.64, 115.10		95.04, 178.43		65.53, 144.57	
	Median	100.54	-38.80	125.58	-2.25	84.82	-29.78
	Q25, Q75	65.63, 154.16	-48.44, -28.42	70.16, 248.26	-21.54, 20.61	55.70, 153.33	-40.18, -22.29
	Min, Max	3.6, 520.3	-71.9, 67.8	18.7, 1154.7	-51.0, 69.1	15.5, 820.4	-61.1, 22.7
	Mean (SD)	127.03 (97.322)	-34.61 (22.375)	195.35 (213.364)	-1.61 (27.833)	149.11 (180.287)	-30.44 (18.092)
	95% CI of Mean	104.32, 149.74	-40.07, -29.14	120.90, 269.80	-12.00, 8.79	69.17, 229.05	-38.68, -22.20

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	1 (1.4)		0		0	
	Geometric Mean (CV%)	69.73 (107.295)		125.05 (117.871)		72.13 (123.800)	
	95% CI of Geometric Mean	56.84, 85.53		90.29, 173.19		47.04, 110.60	
	Median	83.06	-52.87	121.03	-5.35	63.51	-48.22
	Q25, Q75	48.24, 132.05	-61.01, -44.85	66.89, 245.90	-27.67, 10.09	38.02, 126.18	-58.34, -35.07
	Min, Max	1.8, 310.5	-79.8, 289.0	14.1, 1154.7	-46.7, 102.5	14.3, 640.4	-69.7, 6.4
	Mean (SD)	92.62 (63.162)	-47.75 (43.283)	189.58 (208.800)	-4.09 (31.579)	117.12 (145.062)	-45.69 (16.969)
	95% CI of Mean	77.88, 107.36	-58.31, -37.19	116.72, 262.44	-15.89, 7.71	52.80, 181.44	-53.42, -37.96

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	1 (1.4)		0		0	
	Geometric Mean (CV%)	65.81 (101.017)		135.68 (117.497)		68.23 (115.612)	
	95% CI of Geometric Mean	54.11, 80.04		98.03, 187.78		45.34, 102.65	
	Median	81.30	-56.32	114.62	-3.22	67.73	-53.27
	Q25, Q75	45.01, 122.22	-65.63, -45.43	75.45, 293.35	-18.67, 15.44	31.58, 114.55	-64.97, -43.42
	Min, Max	1.7, 321.0	-81.0, 125.5	17.0, 1154.7	-50.6, 108.4	16.8, 604.2	-71.3, 6.9
	Mean (SD)	85.84 (58.288)	-52.70 (26.313)	205.26 (218.307)	0.86 (35.174)	107.07 (131.733)	-49.92 (19.667)
	95% CI of Mean	72.24, 99.45	-59.13, -46.28	129.08, 281.44	-12.28, 14.00	48.65, 165.48	-58.88, -40.97

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	1 (1.4)		0		2 (9.1)	
	Geometric Mean (CV%)	61.46 (103.483)		127.23 (123.388)		55.67 (140.921)	
	95% CI of Geometric Mean	50.36, 75.00		90.95, 177.98		35.01, 88.52	
	Median	71.90	-58.15	124.17	-5.22	61.69	-61.80
	Q25, Q75	42.30, 100.48	-66.93, -49.91	67.19, 266.01	-15.70, 12.89	29.82, 89.23	-68.32, -48.44
	Min, Max	1.6, 294.6	-88.1, 49.9	14.8, 1154.7	-52.8, 85.3	7.1, 505.0	-91.0, -1.7
	Mean (SD)	80.78 (54.875)	-55.76 (19.399)	194.55 (208.882)	0.11 (31.765)	93.26 (114.523)	-57.87 (18.452)
	95% CI of Mean	67.97, 93.58	-60.49, -51.02	121.66, 267.44	-11.76, 11.97	42.48, 144.04	-66.27, -49.46

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	3 (4.1)		1 (2.9)		0	
	Geometric Mean (CV%)	57.04 (112.782)		120.29 (152.188)		54.74 (118.058)	
	95% CI of Geometric Mean	46.17, 70.48		82.09, 176.26		36.17, 82.83	
	Median	68.40	-60.03	107.18	-5.20	53.99	-61.45
	Q25, Q75	38.66, 103.71	-69.39, -55.31	66.02, 294.85	-27.70, 4.64	30.19, 84.87	-66.94, -52.27
	Min, Max	1.2, 240.5	-84.5, 16.3	6.1, 1154.7	-81.8, 114.0	11.9, 392.4	-85.0, -11.1
	Mean (SD)	76.25 (50.141)	-60.23 (14.023)	200.20 (223.989)	-5.58 (38.839)	86.91 (104.779)	-58.86 (17.834)
	95% CI of Mean	64.55, 87.95	-63.66, -56.81	122.04, 278.36	-20.09, 8.93	40.45, 133.37	-66.99, -50.74

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		29		12	
	Missing, n (%)	3 (7.5)		5 (14.7)		1 (7.7)	
	Geometric Mean (CV%)	155.15 (115.323)		136.39 (103.353)		143.67 (107.553)	
	95% CI of Geometric Mean	114.17, 210.83		98.61, 188.63		82.30, 250.77	
	Median	192.37		129.55		106.49	
	Q25, Q75	114.55, 241.58		76.32, 263.97		72.94, 304.32	
	Min, Max	5.0, 643.9		15.3, 470.9		43.8, 603.0	
	Mean (SD)	208.10 (146.669)		183.75 (131.323)		208.97 (200.450)	
	95% CI of Mean	159.20, 257.01		133.79, 233.70		81.61, 336.34	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	37	33	29	13	12
	Missing, n (%)	0	3 (7.5)	1 (2.9)	5 (14.7)	0	1 (7.7)
	BLOQ, n (%)	1 (2.5)		0		1 (7.7)	
	Geometric Mean (CV%)	60.99 (141.182)		159.55 (116.857)		54.96 (158.452)	
	95% CI of Geometric Mean	43.63, 85.25		114.81, 221.71		27.92, 108.18	
	Median	58.37	-65.26	164.46	27.32	52.26	-55.88
	Q25, Q75	38.12, 121.07	-74.79, -36.15	73.49, 356.61	-0.43, 60.53	35.15, 135.48	-76.94, -38.09
	Min, Max	1.6, 740.2	-90.7, 46.5	23.8, 1158.1	-57.6, 238.8	7.2, 381.5	-90.3, -2.9
	Mean (SD)	99.01 (127.232)	-51.95 (32.944)	236.58 (227.507)	42.80 (67.393)	95.27 (108.092)	-55.86 (26.355)
	95% CI of Mean	58.31, 139.70	-62.94, -40.96	155.91, 317.26	17.16, 68.44	29.95, 160.60	-72.61, -39.11

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	35		30		11	
	Missing, n (%)	4 (10.3)		5 (14.3)		1 (8.3)	
	Geometric Mean (CV%)	158.47 (117.264)		135.03 (101.147)		117.16 (106.246)	
	95% CI of Geometric Mean	115.13, 218.13		98.70, 184.75		65.33, 210.08	
	Median	192.37		124.25		104.11	
	Q25, Q75	110.63, 256.90		76.32, 263.97		64.17, 193.14	
	Min, Max	5.0, 643.9		15.3, 470.9		35.3, 561.4	
	Mean (SD)	212.82 (148.836)		180.99 (129.919)		169.15 (168.115)	
	95% CI of Mean	161.69, 263.95		132.47, 229.51		56.21, 282.10	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	35	34	30	11	11
	Missing, n (%)	0	4 (10.3)	1 (2.9)	5 (14.3)	1 (8.3)	1 (8.3)
	BLOQ, n (%)	2 (5.1)		0		2 (18.2)	
	Geometric Mean (CV%)	47.11 (169.294)		142.45 (118.187)		40.39 (247.326)	
	95% CI of Geometric Mean	32.31, 68.69		102.79, 197.40		15.75, 103.52	
	Median	45.79	-70.58	157.27	5.33	55.60	-38.34
	Q25, Q75	26.68, 107.65	-84.61, -43.66	72.59, 269.41	-21.76, 60.39	21.78, 76.19	-91.47, -18.32
	Min, Max	1.8, 671.6	-90.4, 14.2	25.3, 581.8	-53.7, 177.9	3.6, 339.4	-97.8, -5.2
	Mean (SD)	84.75 (114.141)	-61.26 (29.043)	205.89 (167.103)	24.47 (58.456)	80.61 (98.673)	-45.20 (33.784)
	95% CI of Mean	47.74, 121.75	-71.24, -51.28	147.58, 264.20	2.64, 46.30	14.32, 146.91	-67.90, -22.50

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	43		29		9	
	Missing, n (%)	4 (8.5)		3 (9.4)		0	
	Geometric Mean (CV%)	155.34 (117.936)		129.47 (98.154)		108.38 (100.423)	
	95% CI of Geometric Mean	116.54, 207.05		94.72, 176.95		57.04, 205.94	
	Median	194.41		118.96		104.11	
	Q25, Q75	110.63, 241.58		76.32, 258.12		64.17, 165.62	
	Min, Max	5.0, 643.9		15.3, 470.9		35.3, 561.4	
	Mean (SD)	210.49 (148.764)		171.44 (121.033)		153.18 (161.680)	
	95% CI of Mean	164.71, 256.28		125.40, 217.49		28.90, 277.46	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	43	32	29	9	9
	Missing, n (%)	0	4 (8.5)	0	3 (9.4)	0	0
	BLOQ, n (%)	1 (2.1)		0		1 (11.1)	
	Geometric Mean (CV%)	47.53 (144.336)		152.11 (119.154)		48.63 (215.553)	
	95% CI of Geometric Mean	34.80, 64.91		108.38, 213.47		17.69, 133.71	
	Median	47.37	-67.08	164.09	24.87	71.19	-34.62
	Q25, Q75	20.00, 109.43	-84.97, -43.71	91.17, 305.57	-9.32, 51.26	35.25, 85.88	-57.72, 21.82
	Min, Max	2.3, 474.7	-93.9, 83.3	20.8, 542.9	-58.7, 177.9	2.9, 235.3	-98.2, 286.9
	Mean (SD)	79.36 (90.965)	-56.45 (40.351)	214.93 (160.605)	32.30 (67.070)	82.40 (75.326)	-1.97 (116.928)
	95% CI of Mean	52.65, 106.07	-68.87, -44.03	157.02, 272.84	6.78, 57.81	24.49, 140.30	-91.86, 87.91

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	69	30	21
	Missing, n (%)	6 (8.0)	5 (14.3)	3 (12.5)
	BLOQ, n (%)	1 (1.4)	0	0
	Geometric Mean (CV%)	241.93 (113.605)	234.48 (103.427)	227.98 (95.172)
	95% CI of Geometric Mean	194.40, 301.07	170.52, 322.42	158.17, 328.59
	Median	275.60	253.70	233.88
	Q25, Q75	152.52, 460.48	142.20, 492.53	127.31, 405.90
	Min, Max	12.4, 995.9	31.0, 929.3	52.7, 1152.0
	Mean (SD)	328.25 (229.561)	314.10 (223.113)	311.24 (272.656)
	95% CI of Mean	273.10, 383.40	230.79, 397.42	187.13, 435.36

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	Geometric Mean (CV%)	154.56 (95.908)	209.51 (99.717)	157.21 (96.244)
	95% CI of Geometric Mean	128.01, 186.61	156.78, 279.97	109.79, 225.12
	Median	186.06	216.90	168.32
	Q25, Q75	98.17, 273.28	112.30, 369.85	102.48, 274.21
	Min, Max	8.3, 720.2	32.4, 929.3	20.4, 919.2
	Mean (SD)	202.37 (144.662)	285.19 (227.069)	212.05 (191.131)
	95% CI of Mean	168.61, 236.12	205.96, 364.43	127.31, 296.80

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set**

Parameter (units): Total NNAL (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n (%)	1 (1.4)	0	0
	Geometric Mean (CV%)	115.50 (104.033)	203.78 (110.189)	116.68 (95.138)
	95% CI of Geometric Mean	94.58, 141.05	149.29, 278.14	81.73, 166.57
	Median	137.03	223.71	123.42
	Q25, Q75	63.07, 197.12	116.55, 469.56	73.65, 160.51
	Min, Max	3.5, 531.2	28.7, 929.3	25.9, 679.3
	Mean (SD)	152.75 (105.629)	284.32 (218.964)	159.70 (148.171)
	95% CI of Mean	128.10, 177.40	207.91, 360.72	94.00, 225.40

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n (%)	1 (1.4)	0	0
	Geometric Mean (CV%)	108.76 (95.711)	220.36 (110.010)	105.36 (96.355)
	95% CI of Geometric Mean	90.10, 131.28	161.50, 300.67	73.55, 150.91
	Median	130.54	220.99	118.94
	Q25, Q75	70.93, 192.18	113.83, 454.00	66.60, 170.47
	Min, Max	3.7, 537.4	27.9, 1183.3	28.2, 635.2
	Mean (SD)	140.76 (97.758)	313.07 (268.111)	143.84 (132.874)
	95% CI of Mean	117.94, 163.57	219.52, 406.63	84.92, 202.75

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n (%)	1 (1.4)	0	2 (9.1)
	Geometric Mean (CV%)	102.19 (98.130)	202.73 (113.120)	87.29 (123.660)
	95% CI of Geometric Mean	84.36, 123.77	147.69, 278.27	56.94, 133.80
	Median	122.98	205.73	92.76
	Q25, Q75	61.15, 164.28	108.02, 492.66	43.55, 157.61
	Min, Max	3.1, 506.5	25.5, 929.3	8.5, 599.3
	Mean (SD)	133.41 (95.185)	284.46 (218.308)	129.80 (129.197)
	95% CI of Mean	111.20, 155.63	208.29, 360.64	72.51, 187.09

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n (%)	3 (4.1)	1 (2.9)	0
	Geometric Mean (CV%)	97.63 (111.634)	196.38 (146.514)	91.28 (94.218)
	95% CI of Geometric Mean	79.14, 120.44	135.16, 285.33	64.10, 129.98
	Median	127.05	189.06	97.47
	Q25, Q75	60.69, 175.79	97.75, 390.53	49.96, 138.32
	Min, Max	2.9, 468.2	7.4, 1120.6	16.6, 469.0
	Mean (SD)	132.18 (93.462)	305.22 (273.039)	122.05 (102.886)
	95% CI of Mean	110.37, 153.99	209.95, 400.49	76.43, 167.67

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	38	29	12
	Missing, n (%)	2 (5.0)	5 (14.7)	1 (7.7)
	Geometric Mean (CV%)	249.17 (110.966)	223.63 (99.009)	225.07 (89.461)
	95% CI of Geometric Mean	185.61, 334.50	163.29, 306.25	138.27, 366.36
	Median	274.49	240.87	244.36
	Q25, Q75	152.52, 484.40	142.20, 419.49	123.49, 439.14
	Min, Max	12.4, 995.9	31.0, 687.5	70.6, 709.2
	Mean (SD)	334.69 (236.232)	292.90 (193.831)	294.12 (226.556)
	95% CI of Mean	257.04, 412.34	219.17, 366.64	150.17, 438.07

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Day 30	n	40	33	13
	Missing, n (%)	0	1 (2.9)	0
	BLOQ, n (%)	1 (2.5)	0	1 (7.7)
	Geometric Mean (CV%)	98.81 (144.757)	266.22 (110.341)	90.27 (138.635)
	95% CI of Geometric Mean	70.33, 138.83	194.00, 365.32	48.28, 168.77
	Median	97.61	273.70	80.55
	Q25, Q75	58.69, 197.87	155.94, 539.28	48.54, 282.24
	Min, Max	4.4, 1253.2	50.2, 2143.1	19.3, 377.6
	Mean (SD)	166.72 (216.939)	391.02 (402.809)	142.99 (135.210)
	95% CI of Mean	97.34, 236.11	248.19, 533.86	61.28, 224.70

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	37	30	11
	Missing, n (%)	2 (5.1)	5 (14.3)	1 (8.3)
	Geometric Mean (CV%)	247.97 (116.054)	219.96 (97.474)	189.68 (97.950)
	95% CI of Geometric Mean	182.24, 337.41	162.10, 298.45	109.32, 329.10
	Median	296.96	232.95	235.89
	Q25, Q75	152.52, 484.40	136.48, 419.49	100.62, 290.70
	Min, Max	12.4, 995.9	31.0, 687.5	52.7, 709.2
	Mean (SD)	338.74 (240.580)	287.68 (192.599)	255.61 (211.877)
	95% CI of Mean	258.52, 418.96	215.75, 359.60	113.27, 397.96

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Day 60	n	39	34	11
	Missing, n (%)	0	1 (2.9)	1 (8.3)
	BLOQ, n (%)	2 (5.1)	0	2 (18.2)
	Geometric Mean (CV%)	76.52 (169.966)	238.47 (118.901)	67.46 (253.489)
	95% CI of Geometric Mean	52.44, 111.66	171.86, 330.88	26.05, 174.66
	Median	82.97	267.37	96.89
	Q25, Q75	33.28, 186.67	118.65, 498.17	27.67, 143.23
	Min, Max	4.9, 1172.7	28.5, 1145.9	4.0, 613.0
	Mean (SD)	141.06 (198.804)	346.16 (288.326)	138.22 (174.579)
	95% CI of Mean	76.61, 205.51	245.56, 446.77	20.93, 255.50

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	45	29	9
	Missing, n (%)	2 (4.3)	3 (9.4)	0
	Geometric Mean (CV%)	242.51 (117.761)	211.82 (95.443)	175.79 (87.313)
	95% CI of Geometric Mean	183.24, 320.94	155.96, 287.68	98.55, 313.53
	Median	274.59	225.02	235.89
	Q25, Q75	152.52, 484.40	136.48, 388.94	127.31, 253.08
	Min, Max	12.4, 995.9	31.0, 687.5	52.7, 587.6
	Mean (SD)	334.01 (238.501)	274.96 (182.754)	222.44 (161.734)
	95% CI of Mean	262.35, 405.66	205.44, 344.49	98.11, 346.76

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - PP Set****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Day 90	n	47	32	9
	BLOQ, n (%)	1 (2.1)	0	1 (11.1)
	Geometric Mean (CV%)	79.76 (146.979)	252.54 (118.219)	83.25 (301.237)
	95% CI of Geometric Mean	58.20, 109.29	180.26, 353.80	25.88, 267.77
	Median	65.58	324.48	145.40
	Q25, Q75	41.47, 167.16	147.21, 474.18	37.80, 166.44
	Min, Max	5.8, 855.4	37.3, 962.2	3.9, 462.9
	Mean (SD)	136.69 (162.512)	356.81 (272.351)	162.60 (157.054)
	95% CI of Mean	88.97, 184.41	258.61, 455.01	41.88, 283.33

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.1 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Baseline	n	41	26	16	14	12	9
	Missing, n (%)	5 (10.9)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	BLOQ, n (%)	1 (2.4)	0	0	0	0	0
	Geometric Mean (CV%)	128.46 (135.242)	191.55 (78.220)	119.20 (109.519)	189.25 (115.595)	103.63 (87.334)	216.75 (122.992)
	95% CI of Geometric Mean	93.10, 177.25	144.90, 253.22	74.27, 191.32	111.18, 322.13	64.22, 167.20	103.64, 453.32
	Median	169.05	199.24	113.87	232.65	94.50	165.62
	Q25, Q75	108.11, 235.54	110.63, 298.28	67.18, 238.74	97.32, 324.70	55.63, 187.31	118.29, 561.37
	Min, Max	5.0, 544.7	54.1, 643.9	15.3, 470.9	33.4, 1154.7	35.3, 415.5	66.6, 979.6
	Mean (SD)	177.13 (114.941)	239.40 (165.490)	163.94 (128.355)	277.57 (283.386)	135.38 (111.046)	327.03 (316.805)
	95% CI of Mean	140.85, 213.42	172.56, 306.25	95.54, 232.34	113.95, 441.20	64.82, 205.94	83.51, 570.56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.1 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 1	n	44	29	19	15	13	9
	Missing, n (%)	2 (4.3)	0	1 (5.0)	0	2 (13.3)	0
	Geometric Mean (CV%)	77.19 (114.030)	126.49 (82.571)	105.80 (107.927)	169.42 (110.103)	71.51 (80.341)	151.93 (127.493)
	95% CI of Geometric Mean	58.48, 101.88	96.15, 166.41	69.26, 161.61	103.43, 277.52	46.68, 109.55	71.39, 323.32
	Median	93.99	131.99	100.69	159.23	77.43	119.61
	Q25, Q75	59.73, 140.20	77.19, 201.08	48.90, 197.83	79.30, 335.49	51.22, 134.84	70.76, 338.54
	Min, Max	3.6, 342.6	32.1, 520.3	18.7, 514.2	40.4, 1154.7	15.5, 167.8	49.0, 820.4
	Mean (SD)	104.43 (74.047)	161.32 (117.961)	151.25 (138.584)	251.20 (276.827)	87.10 (51.419)	238.67 (257.071)
	95% CI of Mean	81.91, 126.95	116.44, 206.19	84.45, 218.05	97.90, 404.51	56.03, 118.18	41.06, 436.27

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.1 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 1	n	41	26	16	14	12	9
	Missing, n (%)	5 (10.9)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-40.08	-35.93	-9.10	2.87	-30.09	-26.54
	Q25, Q75	-48.91, -28.93	-45.59, -24.71	-21.83, 11.74	-18.24, 22.83	-46.77, -23.99	-39.69, -20.05
	Min, Max	-71.9, 67.8	-56.7, 0.0	-39.5, 50.3	-51.0, 69.1	-61.1, 22.7	-50.7, -9.7
	Mean (SD)	-35.60 (25.820)	-33.04 (15.839)	-4.70 (24.536)	1.93 (31.754)	-31.67 (21.666)	-28.81 (12.944)
	95% CI of Mean	-43.75, -27.44	-39.45, -26.64	-17.78, 8.38	-16.41, 20.27	-45.44, -17.90	-38.76, -18.85

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.1 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 2	n	44	29	19	15	13	9
	Missing, n (%)	2 (4.3)	0	1 (5.0)	0	2 (13.3)	0
	BLOQ, n (%)	1 (2.3)	0	0	0	0	0
	Geometric Mean (CV%)	60.84 (120.224)	85.75 (82.898)	100.60 (114.028)	164.73 (114.379)	52.27 (93.703)	114.87 (139.642)
	95% CI of Geometric Mean	45.64, 81.11	65.12, 112.91	64.79, 156.19	99.26, 273.37	32.35, 84.45	51.64, 255.52
	Median	80.97	93.50	105.14	169.81	53.06	95.49
	Q25, Q75	46.48, 110.29	55.74, 139.14	47.20, 215.07	86.55, 347.24	38.02, 70.08	54.13, 253.79
	Min, Max	1.8, 226.4	19.2, 310.5	14.1, 420.2	39.1, 1154.7	14.3, 167.8	33.0, 640.4
	Mean (SD)	82.11 (52.430)	108.56 (74.836)	142.01 (115.124)	249.84 (280.648)	68.58 (52.004)	187.23 (204.509)
	95% CI of Mean	66.17, 98.06	80.08, 137.03	86.52, 197.50	94.42, 405.26	37.15, 100.02	30.02, 344.43

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.1 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 2	n	41	26	16	14	12	9
	Missing, n (%)	5 (10.9)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-54.63	-50.84	-9.25	-2.93	-47.34	-48.22
	Q25, Q75	-61.05, -42.52	-59.66, -47.46	-25.00, 8.17	-27.67, 16.93	-59.71, -36.47	-54.79, -35.07
	Min, Max	-79.8, 289.0	-73.3, -32.5	-46.7, 102.5	-40.0, 59.0	-69.7, 6.4	-62.9, -24.7
	Mean (SD)	-44.18 (54.678)	-53.39 (10.410)	-5.12 (35.361)	-2.91 (27.911)	-45.75 (19.997)	-45.62 (13.039)
	95% CI of Mean	-61.44, -26.92	-57.60, -49.18	-23.97, 13.72	-19.03, 13.21	-58.46, -33.04	-55.64, -35.59

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.1 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 3	n	44	29	19	15	13	9
	Missing, n (%)	2 (4.3)	0	1 (5.0)	0	2 (13.3)	0
	BLOQ, n (%)	1 (2.3)	0	0	0	0	0
	Geometric Mean (CV%)	57.03 (110.190)	81.79 (81.223)	107.59 (117.854)	182.04 (106.603)	54.53 (80.612)	94.32 (160.834)
	95% CI of Geometric Mean	43.48, 74.79	62.39, 107.23	68.61, 168.70	112.36, 294.93	35.55, 83.63	39.56, 224.84
	Median	74.29	88.12	112.55	236.24	60.86	93.71
	Q25, Q75	42.82, 97.87	53.20, 133.49	58.73, 226.71	95.71, 312.74	31.58, 105.29	43.46, 186.10
	Min, Max	1.7, 223.6	19.9, 321.0	17.0, 605.7	36.8, 1154.7	16.8, 145.5	20.9, 604.2
	Mean (SD)	74.85 (47.378)	102.52 (69.363)	160.57 (157.833)	261.87 (272.329)	67.40 (42.856)	164.36 (191.178)
	95% CI of Mean	60.44, 89.26	76.13, 128.91	84.49, 236.65	111.06, 412.69	41.50, 93.31	17.40, 311.31

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.1 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 3	n	41	26	16	14	12	9
	Missing, n (%)	5 (10.9)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-55.46	-56.68	-11.40	0.31	-51.01	-63.26
	Q25, Q75	-66.22, -44.77	-62.41, -47.35	-27.00, 13.41	-14.51, 19.97	-63.71, -39.16	-68.59, -43.42
	Min, Max	-76.7, 125.5	-81.0, -37.8	-50.6, 108.4	-43.2, 52.4	-65.2, 6.9	-71.3, -14.5
	Mean (SD)	-50.72 (32.553)	-55.84 (10.752)	-1.54 (42.857)	3.61 (25.010)	-47.32 (20.415)	-53.39 (19.242)
	95% CI of Mean	-61.00, -40.44	-60.18, -51.49	-24.38, 21.30	-10.84, 18.05	-60.30, -34.35	-68.18, -38.59

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.1 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 4	n	44	29	19	15	13	9
	Missing, n (%)	2 (4.3)	0	1 (5.0)	0	2 (13.3)	0
	BLOQ, n (%)	1 (2.3)	0	0	0	1 (7.7)	1 (11.1)
	Geometric Mean (CV%)	54.98 (112.028)	72.77 (88.063)	107.50 (110.109)	157.51 (138.670)	45.16 (93.722)	75.32 (218.300)
	95% CI of Geometric Mean	41.79, 72.33	54.54, 97.08	69.96, 165.18	88.76, 279.51	27.94, 72.97	27.23, 208.34
	Median	71.26	74.05	100.51	164.29	50.19	73.36
	Q25, Q75	37.38, 94.77	52.76, 122.90	57.53, 265.23	67.19, 351.46	29.82, 87.29	45.18, 198.51
	Min, Max	1.6, 211.5	15.2, 294.6	14.8, 397.0	25.7, 1154.7	9.6, 131.2	7.1, 505.0
	Mean (SD)	72.42 (45.554)	93.45 (65.423)	147.79 (109.595)	253.77 (284.040)	57.84 (37.960)	144.43 (165.173)
	95% CI of Mean	58.57, 86.28	68.56, 118.34	94.97, 200.62	96.47, 411.07	34.89, 80.78	17.46, 271.40

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.1 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 4	n	41	26	16	14	12	9
	Missing, n (%)	5 (10.9)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-58.15	-57.78	-12.23	1.47	-62.48	-61.80
	Q25, Q75	-66.93, -48.27	-64.61, -50.92	-20.49, 20.04	-10.95, 12.89	-67.80, -45.42	-68.32, -49.44
	Min, Max	-84.1, 49.9	-88.1, -43.9	-52.8, 85.3	-52.8, 38.6	-78.0, -1.7	-91.0, -35.2
	Mean (SD)	-53.34 (22.947)	-59.58 (11.231)	1.62 (37.384)	-1.62 (25.144)	-55.53 (20.286)	-60.98 (16.315)
	95% CI of Mean	-60.58, -46.09	-64.12, -55.04	-18.31, 21.54	-16.14, 12.90	-68.42, -42.64	-73.53, -48.44

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.1 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
Day 5	n	44	29	19	15	13	9
	Missing, n (%)	2 (4.3)	0	1 (5.0)	0	2 (13.3)	0
	BLOQ, n (%)	3 (6.8)	0	0	1 (6.7)	0	0
	Geometric Mean (CV%)	49.99 (128.018)	69.70 (85.740)	104.81 (131.802)	143.22 (183.335)	42.27 (67.631)	79.50 (181.952)
	95% CI of Geometric Mean	37.05, 67.45	52.55, 92.44	64.61, 170.00	73.13, 280.46	29.17, 61.26	31.39, 201.32
	Median	67.50	79.02	96.10	123.09	45.88	80.53
	Q25, Q75	36.07, 98.47	48.79, 118.69	58.87, 242.72	72.00, 300.84	30.19, 60.00	30.28, 185.95
	Min, Max	1.2, 187.6	14.8, 240.5	12.4, 616.5	6.1, 1154.7	13.2, 100.9	11.9, 392.4
	Mean (SD)	68.50 (44.024)	88.01 (57.017)	162.92 (160.062)	247.41 (284.687)	49.48 (27.054)	140.97 (148.850)
	95% CI of Mean	55.11, 81.89	66.32, 109.70	85.77, 240.08	89.75, 405.07	33.13, 65.83	26.55, 255.39

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.1 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=46)	Females (N=29)	Males (N=20)	Females (N=15)	Males (N=15)	Females (N=9)
%Change from baseline to Day 5	n	41	26	16	14	12	9
	Missing, n (%)	5 (10.9)	3 (10.3)	4 (20.0)	1 (6.7)	3 (20.0)	0
	Median	-59.69	-61.42	-13.21	-1.00	-61.35	-63.29
	Q25, Q75	-69.40, -54.47	-68.11, -56.41	-30.15, 2.19	-12.25, 4.64	-69.47, -50.01	-66.88, -54.30
	Min, Max	-84.5, 16.3	-82.6, -43.2	-48.5, 114.0	-81.8, 26.5	-80.7, -11.1	-85.0, -33.1
	Mean (SD)	-58.72 (16.450)	-62.62 (8.747)	-1.74 (44.151)	-9.97 (32.816)	-58.04 (19.110)	-59.96 (17.049)
	95% CI of Mean	-63.92, -53.53	-66.15, -59.08	-25.27, 21.79	-28.92, 8.98	-70.18, -45.89	-73.07, -46.85

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.1 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=28)	Females (N=19)	Males (N=19)	Females (N=13)	Males (N=7)	Females (N=2)
Baseline	n	26	17	17	12	7	2
	Missing, n (%)	2 (7.1)	2 (10.5)	2 (10.5)	1 (7.7)	0	0
	Geometric Mean (CV%)	133.05 (136.406)	196.87 (85.346)	116.02 (105.825)	151.22 (88.619)	80.65 (64.421)	304.91 (105.195)
	95% CI of Geometric Mean	87.93, 201.30	134.59, 287.99	74.30, 181.18	93.22, 245.30	46.77, 139.08	0.13, 711634.52
	Median	182.76	218.97	108.77	186.50	102.27	363.49
	Q25, Q75	114.55, 238.36	110.63, 298.28	75.28, 213.51	95.52, 285.67	43.75, 108.88	165.62, 561.37
	Min, Max	5.0, 544.7	54.1, 643.9	15.3, 470.9	33.4, 384.5	35.3, 193.1	165.6, 561.4
	Mean (SD)	183.60 (120.031)	251.63 (180.577)	158.73 (126.126)	189.46 (116.387)	93.09 (53.346)	363.49 (279.840)
	95% CI of Mean	135.11, 232.08	158.78, 344.48	93.87, 223.58	115.50, 263.41	43.75, 142.43	-2150.77, 2877.76

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.1 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=28)	Females (N=19)	Males (N=19)	Females (N=13)	Males (N=7)	Females (N=2)
Day 90	n	28	19	19	13	7	2
	BLOQ, n (%)	1 (3.6)	0	0	0	0	1 (50.0)
	Geometric Mean (CV%)	43.66 (152.948)	53.88 (135.363)	138.59 (144.926)	174.26 (85.812)	76.02 (105.419)	10.19 (455.904)
	95% CI of Geometric Mean	28.52, 66.84	32.94, 88.11	83.00, 231.43	111.23, 273.00	34.17, 169.10	0.00, 72007929.10
	Median	47.05	47.37	159.33	187.97	81.44	19.10
	Q25, Q75	18.79, 109.72	30.90, 76.03	66.67, 408.57	140.38, 277.95	43.24, 169.25	2.94, 35.25
	Min, Max	2.3, 228.4	7.7, 474.7	20.8, 542.9	31.2, 492.0	17.1, 235.3	2.9, 35.2
	Mean (SD)	70.19 (62.660)	92.87 (122.203)	215.14 (182.546)	214.63 (129.032)	100.48 (75.901)	19.10 (22.842)
	95% CI of Mean	45.89, 94.49	33.96, 151.77	127.15, 303.13	136.66, 292.61	30.28, 170.69	-186.14, 224.33

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.1 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by Sex - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		Males (N=28)	Females (N=19)	Males (N=19)	Females (N=13)	Males (N=7)	Females (N=2)
%Change from baseline to Day 90	n	26	17	17	12	7	2
	Missing, n (%)	2 (7.1)	2 (10.5)	2 (10.5)	1 (7.7)	0	0
	Median	-64.58	-74.94	24.87	13.69	-17.52	-95.97
	Q25, Q75	-84.75, -43.71	-84.97, -44.21	9.03, 51.26	-10.29, 79.46	-51.55, 26.92	-98.22, -93.72
	Min, Max	-92.4, 83.3	-93.9, 24.5	-58.7, 177.9	-54.0, 166.5	-57.7, 286.9	-98.2, -93.7
	Mean (SD)	-52.86 (44.185)	-61.94 (34.212)	31.04 (65.120)	34.08 (72.638)	24.88 (120.171)	-95.97 (3.183)
	95% CI of Mean	-70.71, -35.01	-79.54, -44.34	-2.45, 64.53	-12.08, 80.23	-86.26, 136.03	-124.57, -67.37

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.2 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by CC Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
Baseline	n	39	28	17	13	11	10
	Missing, n (%)	4 (9.3)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	BLOQ, n (%)	1 (2.6)	0	0	0	0	0
	Geometric Mean (CV%)	119.13 (131.538)	206.79 (78.444)	130.93 (108.627)	173.46 (125.903)	116.55 (116.071)	176.92 (108.051)
	95% CI of Geometric Mean	86.08, 164.86	158.09, 270.49	83.15, 206.14	96.25, 312.59	62.66, 216.79	94.30, 331.92
	Median	146.49	221.98	118.96	142.48	96.14	146.23
	Q25, Q75	85.54, 208.46	130.76, 301.77	97.32, 263.97	93.73, 313.23	47.10, 242.70	90.85, 255.42
	Min, Max	5.0, 544.7	44.2, 643.9	15.3, 384.5	33.4, 1154.7	35.3, 561.4	66.6, 979.6
	Mean (SD)	163.30 (109.152)	254.23 (159.550)	175.49 (118.921)	271.22 (301.904)	173.67 (171.340)	265.76 (296.174)
	95% CI of Mean	127.91, 198.69	192.36, 316.10	114.34, 236.63	88.78, 453.66	58.55, 288.78	53.88, 477.63

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.2 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by CC Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
Day 1	n	42	31	20	14	12	10
	Missing, n (%)	1 (2.3)	1 (3.1)	0	1 (6.7)	1 (7.7)	1 (9.1)
	Geometric Mean (CV%)	73.90 (109.856)	129.96 (85.640)	98.25 (93.342)	194.76 (116.250)	79.16 (100.063)	124.72 (119.230)
	95% CI of Geometric Mean	56.00, 97.52	99.00, 170.60	67.83, 142.31	114.19, 332.18	46.63, 134.39	63.64, 244.41
	Median	87.92	146.96	108.59	164.90	74.75	96.16
	Q25, Q75	61.23, 121.93	81.10, 207.96	51.41, 178.53	100.69, 389.74	50.03, 144.09	55.70, 167.81
	Min, Max	3.6, 342.6	22.9, 520.3	18.7, 353.8	40.4, 1154.7	15.5, 338.5	49.0, 820.4
	Mean (SD)	99.55 (75.232)	164.25 (111.840)	129.20 (95.359)	289.85 (293.123)	106.16 (87.389)	200.64 (247.178)
	95% CI of Mean	76.11, 123.00	123.22, 205.28	84.56, 173.83	120.60, 459.10	50.63, 161.69	23.82, 377.47

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.2 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by CC Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
%Change from baseline to Day 1	n	39	28	17	13	11	10
	Missing, n (%)	4 (9.3)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-40.45	-34.11	-17.18	9.19	-30.23	-27.71
	Q25, Q75	-48.91, -28.93	-44.84, -23.86	-21.93, 5.75	-4.49, 20.70	-50.72, -22.29	-34.30, -20.05
	Min, Max	-71.9, 67.8	-56.7, 0.0	-51.0, 50.3	-38.7, 69.1	-61.1, 22.7	-49.9, -9.7
	Mean (SD)	-35.21 (26.943)	-33.76 (14.171)	-9.47 (26.947)	8.67 (26.494)	-32.18 (22.739)	-28.54 (12.049)
	95% CI of Mean	-43.95, -26.47	-39.26, -28.26	-23.33, 4.39	-7.34, 24.69	-47.46, -16.90	-37.16, -19.91

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.2 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by CC Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
Day 2	n	42	31	20	14	12	10
	Missing, n (%)	1 (2.3)	1 (3.1)	0	1 (6.7)	1 (7.7)	1 (9.1)
	BLOQ, n (%)	1 (2.4)	0	0	0	0	0
	Geometric Mean (CV%)	55.70 (114.212)	94.54 (83.720)	99.14 (107.339)	174.23 (119.742)	56.33 (110.031)	97.04 (133.101)
	95% CI of Geometric Mean	41.89, 74.05	72.35, 123.51	65.81, 149.35	101.07, 300.34	31.98, 99.21	47.12, 199.82
	Median	74.02	106.66	112.97	167.23	53.59	82.78
	Q25, Q75	39.79, 90.55	61.01, 158.03	54.22, 186.56	86.58, 366.44	34.18, 108.06	38.02, 167.81
	Min, Max	1.8, 226.4	16.5, 310.5	14.1, 356.2	39.1, 1154.7	14.3, 253.8	33.0, 640.4
	Mean (SD)	74.25 (49.020)	117.50 (71.964)	135.56 (102.235)	266.77 (290.669)	79.56 (70.771)	162.19 (197.083)
	95% CI of Mean	58.97, 89.54	91.10, 143.90	87.70, 183.41	98.93, 434.60	34.59, 124.54	21.20, 303.18

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.2 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by CC Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
%Change from baseline to Day 2	n	39	28	17	13	11	10
	Missing, n (%)	4 (9.3)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-56.32	-50.37	-9.70	0.00	-54.24	-41.81
	Q25, Q75	-62.41, -44.50	-60.73, -44.85	-33.48, 6.25	-10.77, 13.44	-60.37, -38.27	-58.15, -34.62
	Min, Max	-79.8, 289.0	-73.3, -23.7	-46.7, 102.5	-39.2, 59.0	-69.7, 6.4	-61.4, -24.7
	Mean (SD)	-45.61 (55.996)	-50.74 (12.270)	-7.78 (35.971)	0.73 (25.304)	-47.38 (20.712)	-43.84 (12.489)
	95% CI of Mean	-63.77, -27.45	-55.50, -45.97	-26.28, 10.72	-14.56, 16.03	-61.30, -33.46	-52.78, -34.90

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.2 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by CC Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
Day 3	n	42	31	20	14	12	10
	Missing, n (%)	1 (2.3)	1 (3.1)	0	1 (6.7)	1 (7.7)	1 (9.1)
	BLOQ, n (%)	1 (2.4)	0	0	0	0	0
	Geometric Mean (CV%)	54.09 (107.891)	85.85 (81.168)	115.50 (109.796)	170.77 (125.803)	57.98 (91.387)	82.95 (148.037)
	95% CI of Geometric Mean	41.13, 71.14	66.12, 111.45	76.17, 175.14	97.31, 299.69	35.33, 95.12	38.38, 179.27
	Median	66.57	93.26	114.18	176.79	59.21	80.28
	Q25, Q75	32.46, 90.63	55.55, 133.49	63.02, 231.48	80.99, 351.35	33.44, 116.16	31.58, 114.55
	Min, Max	1.7, 223.6	17.2, 321.0	17.0, 605.7	36.8, 1154.7	16.8, 186.1	20.9, 604.2
	Mean (SD)	70.97 (46.985)	106.00 (66.389)	162.33 (140.000)	266.59 (292.312)	75.14 (54.307)	145.38 (184.109)
	95% CI of Mean	56.32, 85.61	81.64, 130.35	96.81, 227.86	97.81, 435.37	40.63, 109.65	13.67, 277.09

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.2 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by CC Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
%Change from baseline to Day 3	n	39	28	17	13	11	10
	Missing, n (%)	4 (9.3)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-57.63	-55.12	-1.66	-12.45	-53.27	-50.40
	Q25, Q75	-65.63, -46.66	-66.47, -45.10	-14.11, 15.44	-20.39, 10.03	-64.97, -34.23	-65.24, -43.42
	Min, Max	-76.7, 125.5	-81.0, -17.8	-50.6, 108.4	-49.0, 52.4	-71.3, 6.9	-68.6, -14.5
	Mean (SD)	-50.99 (32.391)	-55.09 (14.342)	5.52 (39.738)	-5.22 (28.525)	-49.24 (22.606)	-50.67 (17.043)
	95% CI of Mean	-61.50, -40.49	-60.65, -49.52	-14.92, 25.95	-22.47, 12.02	-64.43, -34.05	-62.87, -38.48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.2 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by CC Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
Day 4	n	42	31	20	14	12	10
	Missing, n (%)	1 (2.3)	1 (3.1)	0	1 (6.7)	1 (7.7)	1 (9.1)
	BLOQ, n (%)	1 (2.4)	0	0	0	1 (8.3)	1 (10.0)
	Geometric Mean (CV%)	50.14 (111.828)	80.97 (80.739)	113.15 (117.241)	150.44 (134.553)	50.24 (112.818)	62.97 (188.768)
	95% CI of Geometric Mean	37.86, 66.39	62.44, 105.01	73.22, 174.86	83.64, 270.56	28.25, 89.35	26.08, 152.02
	Median	62.34	95.39	124.17	135.05	56.37	67.10
	Q25, Q75	30.90, 89.67	55.41, 125.04	69.73, 254.58	67.19, 286.72	29.22, 101.03	29.82, 87.29
	Min, Max	1.6, 211.5	15.7, 294.6	14.8, 402.5	34.5, 1154.7	9.6, 198.5	7.1, 505.0
	Mean (SD)	66.95 (45.832)	99.51 (61.040)	158.10 (115.616)	246.61 (293.697)	69.64 (55.392)	121.61 (158.795)
	95% CI of Mean	52.66, 81.24	77.11, 121.90	103.99, 212.22	77.03, 416.19	34.44, 104.84	8.01, 235.21

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.2 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by CC Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
%Change from baseline to Day 4	n	39	28	17	13	11	10
	Missing, n (%)	4 (9.3)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-58.82	-55.94	-2.97	-11.34	-61.80	-62.48
	Q25, Q75	-67.27, -48.79	-63.19, -50.20	-13.12, 35.76	-22.41, 2.94	-68.42, -43.05	-67.18, -49.44
	Min, Max	-84.1, 49.9	-88.1, -30.0	-31.1, 85.3	-52.8, 24.4	-78.0, -1.7	-91.0, -35.2
	Mean (SD)	-54.60 (22.990)	-57.37 (13.089)	10.29 (33.365)	-13.21 (24.799)	-55.31 (21.503)	-60.68 (15.035)
	95% CI of Mean	-62.06, -47.14	-62.45, -52.29	-6.87, 27.45	-28.20, 1.78	-69.76, -40.86	-71.44, -49.92

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.2 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by CC Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
Day 5	n	42	31	20	14	12	10
	Missing, n (%)	1 (2.3)	1 (3.1)	0	1 (6.7)	1 (7.7)	1 (9.1)
	BLOQ, n (%)	3 (7.1)	0	0	1 (7.1)	0	0
	Geometric Mean (CV%)	45.08 (122.153)	78.48 (84.496)	111.98 (137.339)	133.24 (183.580)	48.30 (92.105)	63.61 (156.697)
	95% CI of Geometric Mean	33.46, 60.72	59.95, 102.73	69.16, 181.30	66.08, 268.64	29.35, 79.47	28.67, 141.08
	Median	56.95	94.95	107.86	104.35	51.45	55.48
	Q25, Q75	28.91, 76.58	60.61, 126.32	60.35, 297.84	81.55, 274.87	25.59, 83.59	30.19, 84.87
	Min, Max	1.2, 187.6	12.5, 240.5	12.4, 616.5	6.1, 1154.7	13.2, 186.0	11.9, 392.4
	Mean (SD)	61.69 (43.246)	95.98 (52.715)	175.45 (164.580)	235.56 (292.370)	63.07 (48.600)	115.51 (145.132)
	95% CI of Mean	48.21, 75.17	76.64, 115.32	98.42, 252.48	66.75, 404.37	32.19, 93.96	11.68, 219.34

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.2 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by CC Consumption - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=43)	>19 cig/day (N=32)	10-19 cig/day (N=20)	>19 cig/day (N=15)	10-19 cig/day (N=13)	>19 cig/day (N=11)
%Change from baseline to Day 5	n	39	28	17	13	11	10
	Missing, n (%)	4 (9.3)	4 (12.5)	3 (15.0)	2 (13.3)	2 (15.4)	1 (9.1)
	Median	-61.67	-58.96	-2.89	-12.25	-61.26	-62.37
	Q25, Q75	-69.98, -55.94	-63.70, -55.25	-18.54, 25.59	-33.13, 0.00	-72.00, -47.75	-66.94, -54.30
	Min, Max	-84.5, 16.3	-82.6, -27.0	-43.5, 114.0	-81.8, 20.9	-80.7, -11.1	-85.0, -33.1
	Mean (SD)	-60.85 (15.886)	-59.37 (11.142)	5.26 (41.461)	-19.75 (31.133)	-57.21 (19.445)	-60.68 (16.725)
	95% CI of Mean	-66.01, -55.70	-63.70, -55.05	-16.06, 26.58	-38.57, -0.94	-70.28, -44.15	-72.65, -48.71

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.2 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by CC Consumption - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=21)	>19 cig/day (N=26)	10-19 cig/day (N=19)	>19 cig/day (N=13)	10-19 cig/day (N=6)	>19 cig/day (N=3)
Baseline	n	19	24	17	12	6	3
	Missing, n (%)	2 (9.5)	2 (7.7)	2 (10.5)	1 (7.7)	0	0
	Geometric Mean (CV%)	109.71 (149.063)	204.58 (80.244)	130.93 (108.627)	127.42 (88.998)	101.89 (138.880)	122.63 (26.668)
	95% CI of Geometric Mean	65.13, 184.79	151.90, 275.52	83.15, 206.14	78.43, 207.02	34.33, 302.42	63.94, 235.17
	Median	146.49	221.98	118.96	117.49	84.14	108.88
	Q25, Q75	108.11, 214.56	143.85, 301.77	97.32, 263.97	75.80, 244.32	43.75, 193.14	102.27, 165.62
	Min, Max	5.0, 544.7	44.2, 643.9	15.3, 384.5	33.4, 470.9	35.3, 561.4	102.3, 165.6
	Mean (SD)	157.69 (118.437)	252.29 (159.086)	175.49 (118.921)	165.71 (129.062)	166.98 (201.629)	125.59 (34.822)
	95% CI of Mean	100.60, 214.78	185.11, 319.47	114.34, 236.63	83.71, 247.72	-44.63, 378.58	39.08, 212.09

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.2 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by CC Consumption - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=21)	>19 cig/day (N=26)	10-19 cig/day (N=19)	>19 cig/day (N=13)	10-19 cig/day (N=6)	>19 cig/day (N=3)
Day 90	n	21	26	19	13	6	3
	BLOQ, n (%)	1 (4.8)	0	0	0	0	1 (33.3)
	Geometric Mean (CV%)	35.27 (159.523)	60.49 (123.277)	142.15 (131.583)	167.92 (106.462)	74.28 (125.896)	20.85 (422.278)
	95% CI of Geometric Mean	21.13, 58.85	41.02, 89.20	87.68, 230.45	99.23, 284.16	26.71, 206.55	0.29, 1470.74
	Median	30.90	53.93	159.33	186.01	83.66	43.24
	Q25, Q75	18.25, 94.79	29.78, 136.63	67.03, 313.89	118.81, 277.95	35.25, 169.25	2.94, 71.19
	Min, Max	2.3, 206.8	15.8, 474.7	20.8, 542.9	31.2, 528.2	17.1, 235.3	2.9, 71.2
	Mean (SD)	57.83 (54.120)	96.74 (110.357)	205.50 (153.880)	228.73 (175.409)	104.04 (83.199)	39.12 (34.307)
	95% CI of Mean	33.19, 82.47	52.17, 141.32	131.32, 279.67	122.72, 334.73	16.72, 191.35	-46.10, 124.35

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.1.2 Descriptive Statistics of Total NNAL Urinary Concentration Adjusted for Creatinine (pg/mg creat) in 24-hour Urine Collection by CC Consumption - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2		mCC		SA	
		10-19 cig/day (N=21)	>19 cig/day (N=26)	10-19 cig/day (N=19)	>19 cig/day (N=13)	10-19 cig/day (N=6)	>19 cig/day (N=3)
%Change from baseline to Day 90	n	19	24	17	12	6	3
	Missing, n (%)	2 (9.5)	2 (7.7)	2 (10.5)	1 (7.7)	0	0
	Median	-65.62	-69.96	24.87	18.70	2.15	-57.72
	Q25, Q75	-89.55, -43.71	-84.92, -42.19	0.77, 45.51	-10.29, 94.92	-51.55, 26.92	-98.22, -34.62
	Min, Max	-92.9, 83.3	-93.9, 24.5	-58.7, 177.9	-54.0, 159.0	-93.7, 286.9	-98.2, -34.6
	Mean (SD)	-53.95 (47.150)	-58.43 (34.987)	28.09 (64.241)	38.25 (73.358)	28.80 (134.355)	-63.52 (32.197)
	95% CI of Mean	-76.68, -31.22	-73.21, -43.65	-4.94, 61.13	-8.36, 84.87	-112.20, 169.80	-143.51, 16.46

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		36		36	
	Missing, n (%)	9 (11.3)		5 (12.2)		3 (7.7)	
	BLOQ, n (%)	1 (1.4)		0		0	
	Geometric Mean (CV%)	153.73 (114.507)		160.50 (114.605)		144.49 (111.580)	
	95% CI of Geometric Mean	123.78, 190.92		117.73, 218.81		106.58, 195.88	
	Median	187.11		154.08		134.79	
	Q25, Q75	108.94, 256.90		95.52, 325.94		85.08, 260.02	
	Min, Max	5.0, 643.9		15.3, 1154.7		15.5, 979.6	
	Mean (SD)	206.47 (145.003)		235.29 (229.950)		210.99 (202.221)	
	95% CI of Mean	172.14, 240.79		157.48, 313.10		142.56, 279.42	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	95.95 (106.882)		143.83 (113.322)		96.48 (121.832)	
	95% CI of Geometric Mean	78.70, 116.98		107.55, 192.35		70.19, 132.61	
	Median	100.54	-38.80	134.70	-1.54	90.91	-30.09
	Q25, Q75	65.63, 156.47	-48.44, -28.42	76.24, 322.73	-17.97, 17.45	55.70, 161.48	-46.31, -20.33
	Min, Max	3.6, 520.3	-71.9, 67.8	18.7, 1154.7	-51.0, 69.1	6.3, 820.4	-63.6, 22.7
	Mean (SD)	130.85 (104.096)	-34.79 (21.896)	215.85 (227.620)	-0.44 (26.121)	147.72 (162.193)	-30.85 (20.810)
	95% CI of Mean	107.22, 154.48	-39.98, -29.61	143.04, 288.65	-9.29, 8.40	93.64, 201.81	-37.90, -23.80

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	1 (1.3)		0		1 (2.7)	
	Geometric Mean (CV%)	71.59 (108.588)		137.67 (117.451)		71.42 (158.054)	
	95% CI of Geometric Mean	58.59, 87.47		102.21, 185.43		49.18, 103.73	
	Median	83.06	-52.39	133.36	-5.96	70.08	-48.44
	Q25, Q75	49.82, 132.85	-61.01, -44.85	86.57, 296.12	-15.76, 8.17	37.11, 146.30	-61.71, -34.65
	Min, Max	1.8, 432.8	-79.8, 289.0	14.1, 1154.7	-46.7, 102.5	2.1, 640.4	-86.6, 6.4
	Mean (SD)	96.75 (73.297)	-47.79 (42.134)	207.04 (216.121)	-3.59 (29.160)	121.54 (140.814)	-44.21 (24.917)
	95% CI of Mean	80.11, 113.39	-57.77, -37.81	137.91, 276.16	-13.46, 6.28	74.59, 168.50	-52.64, -35.77

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	1 (1.3)		0		1 (2.7)	
	Geometric Mean (CV%)	67.62 (102.770)		150.55 (116.540)		69.54 (142.536)	
	95% CI of Geometric Mean	55.77, 82.00		111.95, 202.46		48.94, 98.79	
	Median	81.30	-56.32	148.10	-0.83	69.66	-54.21
	Q25, Q75	45.01, 123.79	-65.63, -44.77	86.38, 309.40	-14.31, 13.41	34.98, 127.03	-65.11, -36.27
	Min, Max	1.7, 398.5	-81.0, 125.5	17.0, 1154.7	-50.6, 108.4	2.5, 604.2	-84.1, 6.9
	Mean (SD)	89.89 (67.760)	-52.60 (25.696)	225.46 (230.381)	3.49 (35.798)	113.86 (132.713)	-46.93 (25.801)
	95% CI of Mean	74.50, 105.27	-58.68, -46.51	151.78, 299.15	-8.63, 15.60	69.61, 158.11	-55.66, -38.20

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	1 (1.3)		0		3 (8.1)	
	Geometric Mean (CV%)	62.98 (104.956)		141.67 (122.597)		61.28 (158.435)	
	95% CI of Geometric Mean	51.79, 76.60		104.28, 192.45		42.17, 89.04	
	Median	71.90	-58.15	146.74	-1.53	63.06	-60.47
	Q25, Q75	42.30, 103.26	-66.93, -49.91	82.02, 267.40	-14.73, 8.81	31.48, 127.03	-67.75, -42.69
	Min, Max	1.6, 368.3	-88.1, 49.9	14.8, 1154.7	-52.8, 91.7	3.1, 556.6	-91.0, 0.0
	Mean (SD)	84.25 (63.273)	-55.78 (19.013)	215.44 (224.276)	2.17 (32.981)	105.54 (123.841)	-51.75 (26.250)
	95% CI of Mean	69.89, 98.62	-60.28, -51.27	143.71, 287.17	-8.99, 13.34	64.25, 146.84	-60.64, -42.87

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	3 (3.9)		1 (2.5)		1 (2.7)	
	Geometric Mean (CV%)	58.37 (113.301)		135.45 (148.566)		58.20 (144.341)	
	95% CI of Geometric Mean	47.48, 71.74		95.90, 191.31		40.86, 82.92	
	Median	68.40	-60.03	121.84	-3.20	60.00	-61.83
	Q25, Q75	38.66, 104.29	-69.39, -55.18	72.66, 297.84	-19.27, 11.60	28.09, 100.93	-72.51, -44.28
	Min, Max	1.2, 298.7	-84.5, 16.3	6.1, 1154.7	-81.8, 114.0	3.6, 556.6	-87.0, 0.0
	Mean (SD)	78.91 (55.696)	-60.26 (13.781)	222.06 (242.483)	-2.33 (38.531)	98.91 (119.214)	-53.75 (26.690)
	95% CI of Mean	66.26, 91.56	-63.52, -56.99	144.51, 299.62	-15.37, 10.71	59.15, 138.66	-62.79, -44.72

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	2 (2.6)		0		2 (5.4)	
	Geometric Mean (CV%)	69.93 (145.332)		186.25 (126.899)		71.35 (212.881)	
	95% CI of Geometric Mean	54.91, 89.07		136.15, 254.77		46.13, 110.36	
	Median	74.95	-50.22	194.27	27.26	76.04	-39.77
	Q25, Q75	39.59, 136.30	-71.09, -18.70	77.95, 411.44	-0.21, 54.32	38.86, 163.48	-66.52, -2.12
	Min, Max	1.6, 740.2	-90.7, 190.7	23.8, 1158.1	-57.6, 238.8	1.8, 1019.8	-95.6, 11.5
	Mean (SD)	112.74 (122.664)	-42.71 (42.521)	289.28 (288.865)	39.29 (61.509)	139.69 (187.332)	-39.36 (32.357)
	95% CI of Mean	84.89, 140.58	-52.78, -32.64	196.90, 381.67	18.47, 60.10	77.22, 202.15	-50.31, -28.41

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	3 (3.9)		0		3 (8.1)	
	Geometric Mean (CV%)	63.25 (158.168)		171.88 (131.765)		76.91 (227.553)	
	95% CI of Geometric Mean	49.05, 81.55		124.70, 236.91		49.04, 120.62	
	Median	64.54	-55.44	204.36	15.73	77.16	-33.09
	Q25, Q75	31.73, 137.61	-82.18, -24.30	80.75, 367.83	-19.22, 58.50	46.38, 167.39	-46.25, -8.55
	Min, Max	1.8, 671.6	-90.4, 94.6	25.3, 1154.7	-53.7, 177.9	2.2, 1255.2	-97.8, 28.1
	Mean (SD)	106.69 (117.740)	-45.61 (42.543)	266.16 (257.240)	26.02 (54.569)	153.91 (220.372)	-32.64 (32.569)
	95% CI of Mean	79.96, 133.41	-55.68, -35.53	183.88, 348.43	7.55, 44.49	80.43, 227.39	-43.66, -21.61

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n (%)	2 (2.6)		0		3 (8.1)	
	Geometric Mean (CV%)	61.34 (167.486)		182.52 (134.554)		83.41 (219.095)	
	95% CI of Geometric Mean	47.18, 79.75		131.85, 252.64		53.60, 129.78	
	Median	71.27	-53.29	191.46	25.02	88.48	-29.52
	Q25, Q75	28.44, 138.34	-80.86, -19.29	117.06, 398.04	-3.60, 53.69	46.38, 172.57	-55.33, 0.00
	Min, Max	2.3, 530.2	-93.9, 127.5	20.8, 1154.7	-58.7, 177.9	2.9, 962.7	-98.2, 286.9
	Mean (SD)	108.94 (120.090)	-44.15 (46.893)	278.25 (253.567)	33.30 (62.222)	158.96 (193.583)	-18.24 (65.183)
	95% CI of Mean	81.68, 136.21	-55.25, -33.04	197.15, 359.35	12.24, 54.35	94.41, 223.51	-40.30, 3.82

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	73	36	36
	Missing, n (%)	7 (8.8)	5 (12.2)	3 (7.7)
	BLOQ, n (%)	1 (1.4)	0	0
	Geometric Mean (CV%)	248.45 (111.361)	256.53 (103.256)	236.45 (99.013)
	95% CI of Geometric Mean	201.48, 306.37	192.28, 342.23	178.76, 312.76
	Median	282.51	275.73	242.76
	Q25, Q75	156.56, 460.48	147.40, 536.46	134.94, 461.78
	Min, Max	12.4, 995.9	31.0, 1035.3	44.0, 1241.0
	Mean (SD)	334.24 (229.918)	345.01 (249.669)	328.36 (290.065)
	95% CI of Mean	280.59, 387.88	260.53, 429.49	230.21, 426.51

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 1	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	Geometric Mean (CV%)	157.50 (95.155)	231.24 (99.286)	160.55 (106.323)
	95% CI of Geometric Mean	131.26, 188.99	177.42, 301.37	120.14, 214.57
	Median	186.06	226.86	170.81
	Q25, Q75	101.00, 273.28	145.14, 391.99	90.55, 274.21
	Min, Max	8.3, 720.2	32.4, 929.3	19.2, 1241.0
	Mean (SD)	205.98 (147.549)	312.47 (239.289)	230.15 (237.035)
	95% CI of Mean	172.48, 239.47	235.94, 389.00	151.12, 309.19

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 2	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n (%)	1 (1.3)	0	1 (2.7)
	Geometric Mean (CV%)	118.17 (103.679)	224.14 (108.135)	117.84 (131.081)
	95% CI of Geometric Mean	97.34, 143.47	169.15, 296.99	84.42, 164.48
	Median	137.03	234.63	132.33
	Q25, Q75	64.56, 200.56	140.62, 470.76	69.60, 228.76
	Min, Max	3.5, 531.2	28.7, 929.3	5.5, 1241.0
	Mean (SD)	156.69 (110.337)	308.78 (229.140)	185.91 (221.760)
	95% CI of Mean	131.64, 181.74	235.49, 382.07	111.97, 259.86

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 3	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n (%)	1 (1.3)	0	1 (2.7)
	Geometric Mean (CV%)	111.55 (96.231)	243.20 (106.941)	110.63 (126.190)
	95% CI of Geometric Mean	92.82, 134.05	183.93, 321.55	79.89, 153.18
	Median	130.54	270.17	126.91
	Q25, Q75	71.79, 192.22	133.95, 468.99	68.04, 183.15
	Min, Max	3.7, 537.4	27.9, 1183.3	6.7, 1241.0
	Mean (SD)	145.33 (103.759)	338.12 (272.547)	174.06 (217.232)
	95% CI of Mean	121.77, 168.88	250.95, 425.29	101.62, 246.49

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 4	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n (%)	1 (1.3)	0	3 (8.1)
	Geometric Mean (CV%)	104.23 (98.190)	227.22 (112.084)	98.19 (144.230)
	95% CI of Geometric Mean	86.50, 125.61	170.27, 303.21	68.94, 139.86
	Median	122.98	254.21	112.64
	Q25, Q75	65.14, 167.14	135.26, 498.15	59.46, 179.28
	Min, Max	3.1, 506.5	25.5, 1019.0	7.7, 1241.0
	Mean (SD)	136.71 (99.395)	316.66 (241.539)	164.93 (216.669)
	95% CI of Mean	114.14, 159.27	239.40, 393.91	92.68, 237.17

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 5	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n (%)	3 (3.9)	1 (2.5)	1 (2.7)
	Geometric Mean (CV%)	99.73 (111.061)	222.54 (141.766)	98.72 (125.979)
	95% CI of Geometric Mean	81.37, 122.24	159.07, 311.32	71.32, 136.64
	Median	127.05	257.10	105.78
	Q25, Q75	61.38, 183.49	115.28, 478.94	49.96, 165.21
	Min, Max	2.9, 468.2	7.4, 1120.6	9.4, 1241.0
	Mean (SD)	135.27 (97.046)	337.47 (286.991)	158.20 (208.937)
	95% CI of Mean	113.23, 157.30	245.68, 429.26	88.53, 227.87

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n (%)	2 (2.6)	0	2 (5.4)
	Geometric Mean (CV%)	114.25 (143.087)	295.29 (116.271)	117.42 (195.716)
	95% CI of Geometric Mean	89.90, 145.18	219.68, 396.92	77.27, 178.43
	Median	129.25	297.94	162.83
	Q25, Q75	60.64, 233.69	156.70, 610.89	67.64, 279.50
	Min, Max	4.4, 1253.2	50.2, 2143.1	4.5, 1241.0
	Mean (SD)	185.81 (202.076)	435.03 (407.478)	216.79 (260.250)
	95% CI of Mean	139.94, 231.68	304.71, 565.35	130.01, 303.56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n (%)	3 (3.9)	0	3 (8.1)
	Geometric Mean (CV%)	102.19 (159.096)	280.02 (122.875)	130.24 (235.153)
	95% CI of Geometric Mean	79.19, 131.87	206.03, 380.56	82.48, 205.64
	Median	98.87	322.88	143.23
	Q25, Q75	55.17, 229.33	140.00, 586.11	81.45, 281.20
	Min, Max	4.9, 1172.7	28.5, 1145.9	4.0, 1582.1
	Mean (SD)	174.23 (193.025)	407.12 (323.741)	266.88 (353.669)
	95% CI of Mean	130.42, 218.05	303.58, 510.66	148.96, 384.81

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.2 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - FAS****Parameter (units): Total NNAL (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n (%)	2 (2.6)	0	3 (8.1)
	Geometric Mean (CV%)	103.19 (164.592)	288.74 (122.575)	136.15 (227.487)
	95% CI of Geometric Mean	79.57, 133.82	212.55, 392.22	86.82, 213.50
	Median	125.04	356.58	166.44
	Q25, Q75	50.31, 229.16	173.02, 605.86	76.85, 270.71
	Min, Max	5.8, 924.2	37.3, 1143.0	3.7, 1241.0
	Mean (SD)	182.56 (201.133)	412.39 (310.389)	256.52 (292.536)
	95% CI of Mean	136.91, 228.22	313.11, 511.66	158.97, 354.06

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		30		21	
	Missing, n (%)	8 (10.7)		5 (14.3)		3 (12.5)	
	BLOQ, n (%)	1 (1.5)		0		0	
	Geometric Mean (CV%)	150.01 (115.699)		147.90 (115.044)		142.18 (112.752)	
	95% CI of Geometric Mean	119.80, 187.83		104.97, 208.39		94.14, 214.73	
	Median	187.11		136.01		118.29	
	Q25, Q75	108.94, 241.58		93.73, 313.23		79.32, 242.70	
	Min, Max	5.0, 643.9		15.3, 1154.7		35.3, 979.6	
	Mean (SD)	201.30 (138.980)		216.97 (218.738)		217.52 (237.431)	
	95% CI of Mean	167.39, 235.20		135.29, 298.65		109.44, 325.60	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	93.92 (106.580)		130.23 (112.157)		97.33 (110.314)	
	95% CI of Geometric Mean	76.64, 115.10		95.04, 178.43		65.53, 144.57	
	Median	100.54	-38.80	125.58	-2.25	84.82	-29.78
	Q25, Q75	65.63, 154.16	-48.44, -28.42	70.16, 248.26	-21.54, 20.61	55.70, 153.33	-40.18, -22.29
	Min, Max	3.6, 520.3	-71.9, 67.8	18.7, 1154.7	-51.0, 69.1	15.5, 820.4	-61.1, 22.7
	Mean (SD)	127.03 (97.322)	-34.61 (22.375)	195.35 (213.364)	-1.61 (27.833)	149.11 (180.287)	-30.44 (18.092)
	95% CI of Mean	104.32, 149.74	-40.07, -29.14	120.90, 269.80	-12.00, 8.79	69.17, 229.05	-38.68, -22.20

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	1 (1.4)		0		0	
	Geometric Mean (CV%)	69.73 (107.295)		125.05 (117.871)		72.13 (123.800)	
	95% CI of Geometric Mean	56.84, 85.53		90.29, 173.19		47.04, 110.60	
	Median	83.06	-52.87	121.03	-5.35	63.51	-48.22
	Q25, Q75	48.24, 132.05	-61.01, -44.85	66.89, 245.90	-27.67, 10.09	38.02, 126.18	-58.34, -35.07
	Min, Max	1.8, 310.5	-79.8, 289.0	14.1, 1154.7	-46.7, 102.5	14.3, 640.4	-69.7, 6.4
	Mean (SD)	92.62 (63.162)	-47.75 (43.283)	189.58 (208.800)	-4.09 (31.579)	117.12 (145.062)	-45.69 (16.969)
	95% CI of Mean	77.88, 107.36	-58.31, -37.19	116.72, 262.44	-15.89, 7.71	52.80, 181.44	-53.42, -37.96

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	1 (1.4)		0		0	
	Geometric Mean (CV%)	65.81 (101.017)		135.68 (117.497)		68.23 (115.612)	
	95% CI of Geometric Mean	54.11, 80.04		98.03, 187.78		45.34, 102.65	
	Median	81.30	-56.32	114.62	-3.22	67.73	-53.27
	Q25, Q75	45.01, 122.22	-65.63, -45.43	75.45, 293.35	-18.67, 15.44	31.58, 114.55	-64.97, -43.42
	Min, Max	1.7, 321.0	-81.0, 125.5	17.0, 1154.7	-50.6, 108.4	16.8, 604.2	-71.3, 6.9
	Mean (SD)	85.84 (58.288)	-52.70 (26.313)	205.26 (218.307)	0.86 (35.174)	107.07 (131.733)	-49.92 (19.667)
	95% CI of Mean	72.24, 99.45	-59.13, -46.28	129.08, 281.44	-12.28, 14.00	48.65, 165.48	-58.88, -40.97

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	1 (1.4)		0		2 (9.1)	
	Geometric Mean (CV%)	61.46 (103.483)		127.23 (123.388)		55.67 (140.921)	
	95% CI of Geometric Mean	50.36, 75.00		90.95, 177.98		35.01, 88.52	
	Median	71.90	-58.15	124.17	-5.22	61.69	-61.80
	Q25, Q75	42.30, 100.48	-66.93, -49.91	67.19, 266.01	-15.70, 12.89	29.82, 89.23	-68.32, -48.44
	Min, Max	1.6, 294.6	-88.1, 49.9	14.8, 1154.7	-52.8, 85.3	7.1, 505.0	-91.0, -1.7
	Mean (SD)	80.78 (54.875)	-55.76 (19.399)	194.55 (208.882)	0.11 (31.765)	93.26 (114.523)	-57.87 (18.452)
	95% CI of Mean	67.97, 93.58	-60.49, -51.02	121.66, 267.44	-11.76, 11.97	42.48, 144.04	-66.27, -49.46

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n (%)	3 (4.1)		1 (2.9)		0	
	Geometric Mean (CV%)	57.04 (112.782)		120.29 (152.188)		54.74 (118.058)	
	95% CI of Geometric Mean	46.17, 70.48		82.09, 176.26		36.17, 82.83	
	Median	68.40	-60.03	107.18	-5.20	53.99	-61.45
	Q25, Q75	38.66, 103.71	-69.39, -55.31	66.02, 294.85	-27.70, 4.64	30.19, 84.87	-66.94, -52.27
	Min, Max	1.2, 240.5	-84.5, 16.3	6.1, 1154.7	-81.8, 114.0	11.9, 392.4	-85.0, -11.1
	Mean (SD)	76.25 (50.141)	-60.23 (14.023)	200.20 (223.989)	-5.58 (38.839)	86.91 (104.779)	-58.86 (17.834)
	95% CI of Mean	64.55, 87.95	-63.66, -56.81	122.04, 278.36	-20.09, 8.93	40.45, 133.37	-66.99, -50.74

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=32)		mCC (N=34)		SA (N=8)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		29		8	
	Missing, n (%)	3 (9.4)		5 (14.7)		0	
	Geometric Mean (CV%)	138.59 (130.798)		136.39 (103.353)		149.28 (124.355)	
	95% CI of Geometric Mean	94.79, 202.63		98.61, 188.63		66.52, 334.98	
	Median	152.55		129.55		133.94	
	Q25, Q75	108.94, 225.00		76.32, 263.97		71.74, 377.25	
	Min, Max	5.0, 643.9		15.3, 470.9		43.8, 603.0	
	Mean (SD)	197.71 (159.119)		183.75 (131.323)		226.58 (225.375)	
	95% CI of Mean	137.18, 258.24		133.79, 233.70		38.16, 415.00	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=32)		mCC (N=34)		SA (N=8)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	32	29	33	29	8	8
	Missing, n (%)	0	3 (9.4)	1 (2.9)	5 (14.7)	0	0
	BLOQ, n (%)	1 (3.1)		0		1 (12.5)	
	Geometric Mean (CV%)	57.17 (161.579)		159.55 (116.857)		49.41 (196.919)	
	95% CI of Geometric Mean	37.99, 86.02		114.81, 221.71		17.24, 141.53	
	Median	55.56	-65.26	164.46	27.32	45.56	-51.10
	Q25, Q75	30.65, 121.07	-72.62, -33.03	73.49, 356.61	-0.43, 60.53	27.04, 121.71	-86.82, -35.42
	Min, Max	1.6, 740.2	-90.7, 46.5	23.8, 1158.1	-57.6, 238.8	7.2, 381.5	-90.3, -2.9
	Mean (SD)	100.57 (139.472)	-48.94 (35.806)	236.58 (227.507)	42.80 (67.393)	97.16 (127.791)	-54.99 (31.810)
	95% CI of Mean	50.28, 150.86	-62.57, -35.32	155.91, 317.26	17.16, 68.44	-9.68, 204.00	-81.59, -28.39

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=36)		mCC (N=34)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	33		30		7	
	Missing, n (%)	3 (8.3)		4 (11.8)		0	
	Geometric Mean (CV%)	157.78 (121.422)		135.03 (101.147)		108.94 (123.827)	
	95% CI of Geometric Mean	112.58, 221.12		98.70, 184.75		44.66, 265.72	
	Median	192.37		124.25		102.27	
	Q25, Q75	114.55, 241.58		76.32, 263.97		43.75, 193.14	
	Min, Max	5.0, 643.9		15.3, 470.9		35.3, 561.4	
	Mean (SD)	214.32 (151.984)		180.99 (129.919)		166.52 (184.168)	
	95% CI of Mean	160.42, 268.21		132.47, 229.51		-3.81, 336.85	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=36)		mCC (N=34)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	36	33	33	30	7	7
	Missing, n (%)	0	3 (8.3)	1 (2.9)	4 (11.8)	0	0
	BLOQ, n (%)	2 (5.6)		0		2 (28.6)	
	Geometric Mean (CV%)	46.73 (181.310)		145.06 (119.783)		24.55 (270.120)	
	95% CI of Geometric Mean	31.06, 70.29		103.81, 202.69		6.39, 94.28	
	Median	45.40	-70.58	169.09	5.33	34.49	-43.53
	Q25, Q75	25.17, 118.79	-84.45, -49.73	72.59, 269.41	-21.76, 60.39	3.73, 57.76	-93.86, -20.75
	Min, Max	1.8, 671.6	-90.4, 14.2	25.3, 581.8	-53.7, 177.9	3.6, 183.1	-97.8, -5.2
	Mean (SD)	87.18 (118.452)	-61.58 (28.842)	209.77 (168.139)	24.47 (58.456)	50.75 (62.057)	-55.85 (38.151)
	95% CI of Mean	47.10, 127.26	-71.82, -51.35	150.14, 269.39	2.64, 46.30	-6.64, 108.15	-91.14, -20.57

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=41)		mCC (N=31)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		29		7	
	Missing, n (%)	4 (9.8)		2 (6.5)		0	
	Geometric Mean (CV%)	149.86 (125.114)		129.47 (98.154)		108.94 (123.827)	
	95% CI of Geometric Mean	108.42, 207.13		94.72, 176.95		44.66, 265.72	
	Median	192.37		118.96		102.27	
	Q25, Q75	110.63, 239.55		76.32, 258.12		43.75, 193.14	
	Min, Max	5.0, 643.9		15.3, 470.9		35.3, 561.4	
	Mean (SD)	206.44 (147.797)		171.44 (121.033)		166.52 (184.168)	
	95% CI of Mean	157.15, 255.72		125.40, 217.49		-3.81, 336.85	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=41)		mCC (N=31)		SA (N=7)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	41	37	31	29	7	7
	Missing, n (%)	0	4 (9.8)	0	2 (6.5)	0	0
	BLOQ, n (%)	1 (2.4)		0		1 (14.3)	
	Geometric Mean (CV%)	48.34 (151.756)		152.50 (122.129)		42.47 (284.636)	
	95% CI of Geometric Mean	34.23, 68.26		107.41, 216.51		10.74, 167.86	
	Median	47.37	-65.62	168.85	24.87	43.24	-51.55
	Q25, Q75	25.57, 110.02	-84.97, -41.38	67.03, 313.89	-9.32, 51.26	17.11, 169.25	-93.72, 26.92
	Min, Max	2.3, 474.7	-93.9, 83.3	20.8, 542.9	-58.7, 177.9	2.9, 235.3	-98.2, 286.9
	Mean (SD)	82.59 (95.888)	-53.50 (42.413)	217.34 (162.673)	32.30 (67.070)	83.50 (86.838)	4.91 (134.001)
	95% CI of Mean	52.32, 112.86	-67.65, -39.36	157.66, 277.01	6.78, 57.81	3.19, 163.82	-119.02, 128.85

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population**

Parameter (units): Total NNAL (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	69	30	21
	Missing, n (%)	6 (8.0)	5 (14.3)	3 (12.5)
	BLOQ, n (%)	1 (1.4)	0	0
	Geometric Mean (CV%)	241.93 (113.605)	234.48 (103.427)	227.98 (95.172)
	95% CI of Geometric Mean	194.40, 301.07	170.52, 322.42	158.17, 328.59
	Median	275.60	253.70	233.88
	Q25, Q75	152.52, 460.48	142.20, 492.53	127.31, 405.90
	Min, Max	12.4, 995.9	31.0, 929.3	52.7, 1152.0
	Mean (SD)	328.25 (229.561)	314.10 (223.113)	311.24 (272.656)
	95% CI of Mean	273.10, 383.40	230.79, 397.42	187.13, 435.36

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	Geometric Mean (CV%)	154.56 (95.908)	209.51 (99.717)	157.21 (96.244)
	95% CI of Geometric Mean	128.01, 186.61	156.78, 279.97	109.79, 225.12
	Median	186.06	216.90	168.32
	Q25, Q75	98.17, 273.28	112.30, 369.85	102.48, 274.21
	Min, Max	8.3, 720.2	32.4, 929.3	20.4, 919.2
	Mean (SD)	202.37 (144.662)	285.19 (227.069)	212.05 (191.131)
	95% CI of Mean	168.61, 236.12	205.96, 364.43	127.31, 296.80

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n (%)	1 (1.4)	0	0
	Geometric Mean (CV%)	115.50 (104.033)	203.78 (110.189)	116.68 (95.138)
	95% CI of Geometric Mean	94.58, 141.05	149.29, 278.14	81.73, 166.57
	Median	137.03	223.71	123.42
	Q25, Q75	63.07, 197.12	116.55, 469.56	73.65, 160.51
	Min, Max	3.5, 531.2	28.7, 929.3	25.9, 679.3
	Mean (SD)	152.75 (105.629)	284.32 (218.964)	159.70 (148.171)
	95% CI of Mean	128.10, 177.40	207.91, 360.72	94.00, 225.40

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n (%)	1 (1.4)	0	0
	Geometric Mean (CV%)	108.76 (95.711)	220.36 (110.010)	105.36 (96.355)
	95% CI of Geometric Mean	90.10, 131.28	161.50, 300.67	73.55, 150.91
	Median	130.54	220.99	118.94
	Q25, Q75	70.93, 192.18	113.83, 454.00	66.60, 170.47
	Min, Max	3.7, 537.4	27.9, 1183.3	28.2, 635.2
	Mean (SD)	140.76 (97.758)	313.07 (268.111)	143.84 (132.874)
	95% CI of Mean	117.94, 163.57	219.52, 406.63	84.92, 202.75

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n (%)	1 (1.4)	0	2 (9.1)
	Geometric Mean (CV%)	102.19 (98.130)	202.73 (113.120)	87.29 (123.660)
	95% CI of Geometric Mean	84.36, 123.77	147.69, 278.27	56.94, 133.80
	Median	122.98	205.73	92.76
	Q25, Q75	61.15, 164.28	108.02, 492.66	43.55, 157.61
	Min, Max	3.1, 506.5	25.5, 929.3	8.5, 599.3
	Mean (SD)	133.41 (95.185)	284.46 (218.308)	129.80 (129.197)
	95% CI of Mean	111.20, 155.63	208.29, 360.64	72.51, 187.09

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n (%)	3 (4.1)	1 (2.9)	0
	Geometric Mean (CV%)	97.63 (111.634)	196.38 (146.514)	91.28 (94.218)
	95% CI of Geometric Mean	79.14, 120.44	135.16, 285.33	64.10, 129.98
	Median	127.05	189.06	97.47
	Q25, Q75	60.69, 175.79	97.75, 390.53	49.96, 138.32
	Min, Max	2.9, 468.2	7.4, 1120.6	16.6, 469.0
	Mean (SD)	132.18 (93.462)	305.22 (273.039)	122.05 (102.886)
	95% CI of Mean	110.37, 153.99	209.95, 400.49	76.43, 167.67

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=32)	mCC (N=34)	SA (N=8)
		Value	Value	Value
Baseline	n	30	29	8
	Missing, n (%)	2 (6.3)	5 (14.7)	0
	Geometric Mean (CV%)	216.84 (119.572)	223.63 (99.009)	229.33 (90.759)
	95% CI of Geometric Mean	152.52, 308.28	163.29, 306.25	119.95, 438.44
	Median	244.15	240.87	252.96
	Q25, Q75	131.23, 450.88	142.20, 419.49	123.49, 439.14
	Min, Max	12.4, 995.9	31.0, 687.5	70.6, 650.8
	Mean (SD)	301.97 (229.494)	292.90 (193.831)	294.07 (215.458)
	95% CI of Mean	216.27, 387.67	219.17, 366.64	113.94, 474.20

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=32)	mCC (N=34)	SA (N=8)
		Value	Value	Value
Day 30	n	32	33	8
	Missing, n (%)	0	1 (2.9)	0
	BLOQ, n (%)	1 (3.1)	0	1 (12.5)
	Geometric Mean (CV%)	91.07 (160.629)	266.22 (110.341)	75.24 (145.964)
	95% CI of Geometric Mean	60.61, 136.84	194.00, 365.32	30.80, 183.79
	Median	89.83	273.70	72.79
	Q25, Q75	44.65, 197.87	155.94, 539.28	35.28, 189.35
	Min, Max	4.4, 1253.2	50.2, 2143.1	19.3, 371.8
	Mean (SD)	164.83 (232.901)	391.02 (402.809)	123.24 (132.469)
	95% CI of Mean	80.86, 248.80	248.19, 533.86	12.49, 233.99

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=36)	mCC (N=34)	SA (N=7)
		Value	Value	Value
Baseline	n	34	30	7
	Missing, n (%)	2 (5.6)	4 (11.8)	0
	Geometric Mean (CV%)	255.90 (112.803)	219.96 (97.474)	175.74 (103.374)
	95% CI of Geometric Mean	186.54, 351.04	162.10, 298.45	79.88, 386.66
	Median	299.08	232.95	252.84
	Q25, Q75	152.52, 484.40	136.48, 419.49	70.60, 290.70
	Min, Max	12.4, 995.9	31.0, 687.5	52.7, 587.6
	Mean (SD)	344.90 (242.225)	287.68 (192.599)	233.54 (182.527)
	95% CI of Mean	260.38, 429.42	215.75, 359.60	64.73, 402.36

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=36)	mCC (N=34)	SA (N=7)
		Value	Value	Value
Day 60	n	36	33	7
	Missing, n (%)	0	1 (2.9)	0
	BLOQ, n (%)	2 (5.6)	0	2 (28.6)
	Geometric Mean (CV%)	74.42 (181.589)	244.00 (119.826)	40.58 (268.096)
	95% CI of Geometric Mean	49.45, 111.97	174.61, 340.95	10.61, 155.13
	Median	80.02	292.38	33.74
	Q25, Q75	32.24, 203.56	130.06, 498.17	13.00, 121.50
	Min, Max	4.9, 1172.7	28.5, 1145.9	4.0, 268.8
	Mean (SD)	143.56 (206.751)	353.26 (289.764)	83.10 (94.459)
	95% CI of Mean	73.60, 213.52	250.51, 456.01	-4.27, 170.46

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=41)	mCC (N=31)	SA (N=7)
		Value	Value	Value
Baseline	n	39	29	7
	Missing, n (%)	2 (4.9)	2 (6.5)	0
	Geometric Mean (CV%)	227.33 (123.388)	211.82 (95.443)	175.74 (103.374)
	95% CI of Geometric Mean	166.43, 310.51	155.96, 287.68	79.88, 386.66
	Median	274.39	225.02	252.84
	Q25, Q75	130.17, 450.88	136.48, 388.94	70.60, 290.70
	Min, Max	12.4, 995.9	31.0, 687.5	52.7, 587.6
	Mean (SD)	319.67 (238.522)	274.96 (182.754)	233.54 (182.527)
	95% CI of Mean	242.34, 396.99	205.44, 344.49	64.73, 402.36

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.5.3 Descriptive Statistics of Total NNAL in 24-hour Urine Collection - Compliant Population****Parameter (units): Total NNAL (ng)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=41)	mCC (N=31)	SA (N=7)
		Value	Value	Value
Day 90	n	41	31	7
	BLOQ, n (%)	1 (2.4)	0	1 (14.3)
	Geometric Mean (CV%)	79.58 (157.046)	255.38 (120.761)	70.22 (420.482)
	95% CI of Geometric Mean	55.96, 113.15	180.34, 361.64	14.42, 341.76
	Median	65.58	324.60	102.80
	Q25, Q75	48.25, 167.16	127.00, 494.04	19.70, 367.63
	Min, Max	5.8, 855.4	37.3, 962.2	3.9, 462.9
	Mean (SD)	141.52 (171.847)	362.56 (274.872)	165.88 (181.164)
	95% CI of Mean	87.27, 195.76	261.73, 463.39	-1.68, 333.43

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline, Within 15 Min Prior To Smoking	n	75		35			
	Geometric Mean (CV%)	9.81 (52.993)		11.02 (43.059)			
	95% CI of Geometric Mean	8.75, 11.01		9.56, 12.70			
	Median	10.00		11.00			
	Q25, Q75	8.00, 14.00		10.00, 15.00			
	Min, Max	2.0, 27.0		4.0, 21.0			
	Mean (SD)	10.95 (4.918)		11.86 (4.216)			
	95% CI of Mean	9.81, 12.08		10.40, 13.31			

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline,	n					24	
08:00 - 09:30							
	Geometric Mean (CV%)					8.74 (40.248)	
	95% CI of Geometric Mean					7.41, 10.30	
	Median					9.50	
	Q25, Q75					7.00, 11.50	
	Min, Max					4.0, 15.0	
	Mean (SD)					9.33 (3.213)	
	95% CI of Mean					7.97, 10.69	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline, 12:00 - 13:30	n	75		35		24	
	Geometric Mean (CV%)	19.81 (58.965)		19.55 (53.292)		17.71 (59.935)	
	95% CI of Geometric Mean	17.47, 22.47		16.46, 23.22		14.01, 22.39	
	Median	20.00		21.00		19.50	
	Q25, Q75	15.00, 29.00		18.00, 27.00		12.00, 25.00	
	Min, Max	2.0, 51.0		3.0, 35.0		4.0, 41.0	
	Mean (SD)	22.41 (10.591)		21.43 (7.598)		20.17 (9.748)	
	95% CI of Mean	19.97, 24.86		18.81, 24.04		16.05, 24.29	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline, n		75		35		24	
16:00 - 17:30	Geometric Mean (CV%)	NC		21.29 (49.316)		20.18 (54.096)	
	95% CI of Geometric Mean	NC		18.13, 25.00		16.29, 24.99	
	Median	21.00		22.00		22.50	
	Q25, Q75	15.00, 29.00		18.00, 29.00		17.50, 26.50	
	Min, Max	0.0, 53.0		5.0, 44.0		3.0, 42.0	
	Mean (SD)	22.71 (10.755)		23.23 (8.789)		22.08 (7.874)	
	95% CI of Mean	20.23, 25.19		20.20, 26.25		18.75, 25.41	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline,	n	75		35		24	
20:00 - 21:30							
	Geometric Mean (CV%)	20.88 (56.229)		NC		22.92 (48.813)	
	95% CI of Geometric Mean	18.50, 23.56		NC		18.85, 27.87	
	Median	23.00		25.00		23.50	
	Q25, Q75	16.00, 30.00		16.00, 29.00		19.00, 30.50	
	Min, Max	2.0, 50.0		0.0, 47.0		6.0, 47.0	
	Mean (SD)	23.28 (9.765)		23.91 (10.348)		25.00 (9.637)	
	95% CI of Mean	21.03, 25.53		20.35, 27.47		20.93, 29.07	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1, 12:00 - 13:30	n	75	75	35	35	24	24
	Geometric Mean (CV%)	NC		15.80 (81.987)		6.65 (60.800)	
	95% CI of Geometric Mean	NC		12.35, 20.22		5.24, 8.43	
	Median	6.00	-71.43	20.00	-8.57	7.00	-60.43
	Q25, Q75	4.00, 8.00	-80.00, -64.29	11.00, 27.00	-33.33, 3.23	5.50, 8.50	-76.57, -39.57
	Min, Max	0.0, 24.0	-100.0, 33.3	2.0, 39.0	-75.0, 63.2	1.0, 22.0	-92.3, 25.0
	Mean (SD)	6.29 (3.784)	-68.31 (21.775)	19.20 (10.255)	-11.41 (35.796)	7.58 (4.086)	-54.00 (30.112)
	95% CI of Mean	5.42, 7.17	-73.33, -63.30	15.67, 22.73	-23.71, 0.90	5.85, 9.31	-66.72, -41.28

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1, 16:00 - 17:30	n	75	75	35	35	24	24
	Geometric Mean (CV%)	NC		18.12 (78.434)		3.96 (66.138)	
	95% CI of Geometric Mean	NC		14.28, 22.99		3.07, 5.11	
	Median	4.00	-81.82	19.00	-13.95	4.00	-77.94
	Q25, Q75	3.00, 6.00	-86.84, -71.43	13.00, 29.00	-28.57, 13.33	3.00, 6.00	-86.58, -65.33
	Min, Max	0.0, 12.0	-100.0, 200.0	1.0, 44.0	-80.0, 65.2	1.0, 9.0	-95.0, -33.3
	Mean (SD)	4.33 (2.310)	-75.48 (34.689)	21.31 (10.335)	-9.10 (29.690)	4.58 (2.245)	-75.91 (15.237)
	95% CI of Mean	3.80, 4.87	-83.46, -67.49	17.76, 24.87	-19.31, 1.10	3.63, 5.54	-82.35, -69.47

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1, 20:00 - 21:30	n	75	75	35	35	24	24
	Geometric Mean (CV%)	NC		19.41 (62.267)		NC	
	95% CI of Geometric Mean	NC		15.94, 23.64		NC	
	Median	3.00	-86.84	22.00	-3.70	3.00	-86.86
	Q25, Q75	2.00, 4.00	-90.91, -78.95	16.00, 29.00	-24.14, 15.38	3.00, 4.00	-90.87, -80.95
	Min, Max	0.0, 8.0	-100.0, -61.1	3.0, 38.0	-71.4, 300.0	0.0, 5.0	-100.0, -50.0
	Mean (SD)	3.21 (1.913)	-84.92 (9.914)	21.86 (8.678)	4.93 (60.262)	3.17 (1.373)	-84.47 (11.147)
	95% CI of Mean	2.77, 3.66	-87.21, -82.63	18.87, 24.84	-15.77, 25.64	2.58, 3.75	-89.18, -79.76

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2, Within 15 Min Prior To Smoking	n	75	75	35	35		
	Geometric Mean (CV%)	NC		9.75 (50.970)			
	95% CI of Geometric Mean	NC		8.26, 11.51			
	Median	2.00	-76.92	10.00	-7.14		
	Q25, Q75	2.00, 3.00	-84.62, -66.67	9.00, 13.00	-22.22, 6.67		
	Min, Max	0.0, 13.0	-100.0, 44.4	2.0, 21.0	-69.2, 50.0		
	Mean (SD)	2.61 (1.724)	-72.12 (22.675)	10.69 (4.043)	-7.80 (24.653)		
	95% CI of Mean	2.21, 3.01	-77.34, -66.90	9.29, 12.08	-16.27, 0.67		

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2, 08:00 - 09:30	n					24	24
	Geometric Mean (CV%)					2.64 (35.594)	
	95% CI of Geometric Mean					2.28, 3.06	
	Median					3.00	-70.71
	Q25, Q75					2.00, 3.00	-75.00, -61.25
	Min, Max					1.0, 5.0	-85.7, -25.0
	Mean (SD)					2.79 (0.932)	-66.58 (15.707)
	95% CI of Mean					2.39, 3.19	-73.21, -59.94

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2, 12:00 - 13:30	n	75	75	35	35	24	24
	Geometric Mean (CV%)	NC		14.82 (57.724)		NC	
	95% CI of Geometric Mean	NC		12.32, 17.82		NC	
	Median	2.00	-90.00	16.00	-22.22	3.00	-87.87
	Q25, Q75	1.00, 3.00	-93.75, -83.33	11.00, 24.00	-42.86, 0.00	2.00, 3.00	-91.81, -76.96
	Min, Max	0.0, 5.0	-100.0, 66.7	3.0, 31.0	-68.8, 66.7	0.0, 8.0	-100.0, -27.3
	Mean (SD)	2.32 (1.387)	-86.10 (20.006)	16.74 (7.736)	-17.82 (33.761)	2.83 (1.660)	-81.83 (16.641)
	95% CI of Mean	2.00, 2.64	-90.71, -81.49	14.08, 19.41	-29.42, -6.22	2.13, 3.54	-88.86, -74.80

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2, 16:00 - 17:30	n	75	75	35	35	24	24
	Geometric Mean (CV%)	NC		18.45 (52.180)		2.51 (55.841)	
	95% CI of Geometric Mean	NC		15.58, 21.85		2.01, 3.14	
	Median	3.00	-88.89	19.00	-6.67	2.50	-88.68
	Q25, Q75	1.00, 3.00	-94.59, -82.61	14.00, 26.00	-26.32, 7.14	2.00, 3.00	-92.15, -80.91
	Min, Max	0.0, 5.0	-100.0, 0.0	4.0, 44.0	-64.7, 62.5	1.0, 9.0	-96.6, 0.0
	Mean (SD)	2.36 (1.353)	-86.05 (14.937)	20.29 (7.918)	-9.45 (25.711)	2.88 (1.702)	-82.63 (19.712)
	95% CI of Mean	2.04, 2.68	-89.49, -82.60	17.56, 23.01	-18.28, -0.61	2.15, 3.60	-90.96, -74.30

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2, 20:00 - 21:30	n	75	75	35	35	24	24
	Geometric Mean (CV%)	NC		19.79 (56.227)		NC	
	95% CI of Geometric Mean	NC		16.53, 23.70		NC	
	Median	2.00	-90.00	23.00	-5.13	2.00	-90.28
	Q25, Q75	1.00, 3.00	-94.44, -84.85	16.00, 28.00	-27.66, 25.00	1.00, 3.00	-96.71, -86.61
	Min, Max	0.0, 6.0	-100.0, -50.0	4.0, 38.0	-60.0, 400.0	0.0, 5.0	-100.0, -66.7
	Mean (SD)	2.25 (1.377)	-88.88 (9.047)	22.06 (9.000)	8.52 (74.536)	1.88 (1.362)	-90.21 (8.671)
	95% CI of Mean	1.93, 2.58	-90.96, -86.79	18.96, 25.15	-17.09, 34.13	1.30, 2.45	-93.87, -86.54

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3, Within 15 Min Prior To Smoking	n	75	75	35	35		
	Geometric Mean (CV%)	NC		10.02 (49.484)			
	95% CI of Geometric Mean	NC		8.53, 11.77			
	Median	2.00	-80.00	10.00	-9.09		
	Q25, Q75	1.00, 3.00	-84.62, -70.00	8.00, 15.00	-18.18, 0.00		
	Min, Max	0.0, 5.0	-100.0, 0.0	3.0, 21.0	-44.4, 60.0		
	Mean (SD)	2.19 (1.010)	-75.97 (16.441)	11.00 (4.400)	-7.01 (20.629)		
	95% CI of Mean	1.95, 2.42	-79.76, -72.18	9.48, 12.52	-14.10, 0.09		

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3, 08:00 - 09:30	n					24	24
	Geometric Mean (CV%)					NC	
	95% CI of Geometric Mean					NC	
	Median					2.00	-72.73
	Q25, Q75					2.00, 3.00	-80.00, -62.50
	Min, Max					0.0, 5.0	-100.0, -25.0
	Mean (SD)					2.38 (1.056)	-70.81 (16.937)
	95% CI of Mean					1.92, 2.83	-77.97, -63.66

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3, 12:00 - 13:30	n	75	75	35	35	24	24
	Geometric Mean (CV%)	NC		15.69 (68.922)		NC	
	95% CI of Geometric Mean	NC		12.66, 19.44		NC	
	Median	2.00	-90.00	17.00	-19.23	2.50	-88.56
	Q25, Q75	1.00, 3.00	-93.75, -81.82	12.00, 26.00	-38.46, 7.41	1.50, 4.00	-94.49, -71.66
	Min, Max	0.0, 6.0	-100.0, 0.0	3.0, 34.0	-75.0, 66.7	0.0, 7.0	-100.0, -50.0
	Mean (SD)	2.43 (1.348)	-85.49 (14.978)	18.34 (9.013)	-12.73 (34.343)	2.75 (1.848)	-83.45 (14.604)
	95% CI of Mean	2.11, 2.74	-88.94, -82.03	15.24, 21.44	-24.53, -0.92	1.96, 3.54	-89.62, -77.28

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3, 16:00 - 17:30	n	75	75	35	35	24	24
	Geometric Mean (CV%)	NC		19.59 (53.693)		2.40 (49.377)	
	95% CI of Geometric Mean	NC		16.48, 23.30		1.96, 2.92	
	Median	3.00	-87.88	22.00	0.00	3.00	-86.86
	Q25, Q75	1.00, 3.00	-94.74, -81.25	16.00, 27.00	-23.33, 16.13	2.00, 3.00	-91.31, -82.09
	Min, Max	0.0, 6.0	-100.0, 100.0	4.0, 44.0	-64.7, 68.8	1.0, 4.0	-96.6, -33.3
	Mean (SD)	2.49 (1.389)	-83.82 (24.368)	21.69 (8.788)	-2.79 (31.171)	2.63 (1.014)	-84.97 (12.621)
	95% CI of Mean	2.17, 2.82	-89.43, -78.21	18.66, 24.71	-13.50, 7.92	2.19, 3.06	-90.30, -79.63

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3, 20:00 - 21:30	n	75	75	35	35	24	24
	Geometric Mean (CV%)	NC		20.60 (45.258)		NC	
	95% CI of Geometric Mean	NC		17.76, 23.90		NC	
	Median	2.00	-90.00	22.00	-7.14	3.00	-89.47
	Q25, Q75	1.00, 4.00	-94.44, -83.33	17.00, 28.00	-28.57, 20.00	2.00, 4.00	-91.74, -82.68
	Min, Max	0.0, 7.0	-100.0, -57.1	5.0, 43.0	-39.3, 900.0	0.0, 8.0	-100.0, -50.0
	Mean (SD)	2.31 (1.551)	-88.81 (8.734)	22.29 (8.199)	24.53 (156.280)	2.92 (1.692)	-85.85 (11.338)
	95% CI of Mean	1.94, 2.67	-90.82, -86.79	19.46, 25.11	-29.15, 78.22	2.20, 3.64	-90.64, -81.06

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4, Within 15 Min Prior To Smoking	n	75	75	35	35		
	Geometric Mean (CV%)	NC		10.12 (50.244)			
	95% CI of Geometric Mean	NC		8.59, 11.92			
	Median	2.00	-80.00	11.00	-9.09		
	Q25, Q75	1.00, 3.00	-88.89, -72.73	8.00, 13.00	-20.00, 10.00		
	Min, Max	0.0, 6.0	-100.0, -28.6	2.0, 21.0	-60.0, 160.0		
	Mean (SD)	2.05 (1.185)	-78.67 (13.933)	11.06 (4.051)	-2.90 (37.027)		
	95% CI of Mean	1.78, 2.33	-81.88, -75.46	9.66, 12.45	-15.63, 9.82		

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4, 08:00 - 09:30	n					24	24
	Geometric Mean (CV%)					2.21 (46.960)	
	95% CI of Geometric Mean					1.83, 2.68	
	Median					2.00	-72.73
	Q25, Q75					2.00, 3.00	-82.31, -63.07
	Min, Max					1.0, 4.0	-92.9, -40.0
	Mean (SD)					2.42 (0.975)	-71.15 (13.789)
	95% CI of Mean					2.00, 2.83	-76.98, -65.33

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4, 12:00 - 13:30	n	75	75	35	35	24	24
	Geometric Mean (CV%)	NC		15.74 (68.523)		NC	
	95% CI of Geometric Mean	NC		12.71, 19.48		NC	
	Median	3.00	-90.00	18.00	-20.00	2.00	-90.45
	Q25, Q75	2.00, 3.00	-93.62, -83.33	13.00, 23.00	-30.00, 0.00	2.00, 3.50	-91.95, -76.47
	Min, Max	0.0, 9.0	-100.0, 66.7	1.0, 36.0	-83.3, 133.3	0.0, 5.0	-100.0, -25.0
	Mean (SD)	2.59 (1.629)	-83.89 (22.825)	17.89 (7.518)	-12.39 (36.755)	2.58 (1.283)	-82.80 (15.787)
	95% CI of Mean	2.21, 2.97	-89.15, -78.63	15.30, 20.47	-25.02, 0.24	2.04, 3.13	-89.48, -76.13

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4, 16:00 - 17:30	n	75	75	35	35	24	24
	Geometric Mean (CV%)	NC		19.80 (51.499)		NC	
	95% CI of Geometric Mean	NC		16.76, 23.39		NC	
	Median	2.00	-88.89	21.00	-5.00	3.00	-88.68
	Q25, Q75	2.00, 3.00	-93.75, -81.25	16.00, 28.00	-18.18, 13.04	2.00, 3.00	-92.45, -82.29
	Min, Max	0.0, 9.0	-100.0, 100.0	5.0, 44.0	-68.0, 106.3	0.0, 6.0	-100.0, -33.3
	Mean (SD)	2.44 (1.613)	-83.98 (24.635)	21.91 (9.411)	-1.63 (32.823)	2.50 (1.180)	-85.73 (13.003)
	95% CI of Mean	2.06, 2.82	-89.65, -78.31	18.68, 25.15	-12.91, 9.65	2.00, 3.00	-91.22, -80.23

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4, 20:00 - 21:30	n	75	75	35	35	24	24
	Geometric Mean (CV%)	NC		20.82 (48.086)		2.19 (53.792)	
	95% CI of Geometric Mean	NC		17.80, 24.36		1.76, 2.71	
	Median	2.00	-90.48	20.00	0.00	2.00	-90.33
	Q25, Q75	1.00, 3.00	-96.00, -85.71	17.00, 29.00	-21.74, 21.43	2.00, 3.00	-93.84, -84.96
	Min, Max	0.0, 6.0	-100.0, -50.0	6.0, 39.0	-65.0, 600.0	1.0, 6.0	-97.8, 0.0
	Mean (SD)	2.07 (1.465)	-89.24 (9.795)	22.74 (8.807)	18.75 (106.645)	2.46 (1.216)	-85.96 (19.206)
	95% CI of Mean	1.72, 2.41	-91.50, -86.98	19.71, 25.77	-17.89, 55.39	1.94, 2.98	-94.07, -77.84

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, Within 15 Min Prior To Smoking	n	75	75	35	35		
	Geometric Mean (CV%)	NC		10.55 (51.320)			
	95% CI of Geometric Mean	NC		8.93, 12.47			
	Median	2.00	-77.78	11.00	-8.33		
	Q25, Q75	2.00, 3.00	-84.62, -70.00	9.00, 15.00	-14.29, 11.76		
	Min, Max	0.0, 5.0	-100.0, -25.0	3.0, 21.0	-58.3, 160.0		
	Mean (SD)	2.39 (1.065)	-74.97 (14.224)	11.60 (4.454)	1.06 (36.933)		
	95% CI of Mean	2.14, 2.64	-78.25, -71.70	10.07, 13.13	-11.64, 13.75		

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 08:00 - 09:30	n					24	24
	Geometric Mean (CV%)					2.45 (34.210)	
	95% CI of Geometric Mean					2.13, 2.83	
	Median					2.00	-72.73
	Q25, Q75					2.00, 3.00	-76.39, -65.15
	Min, Max					1.0, 4.0	-85.7, -20.0
	Mean (SD)					2.58 (0.830)	-68.90 (15.597)
	95% CI of Mean					2.23, 2.94	-75.49, -62.31

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 12:00 - 13:30	n	75	75	35	35	24	24
	Geometric Mean (CV%)	NC		17.46 (52.508)		NC	
	95% CI of Geometric Mean	NC		14.73, 20.69		NC	
	Median	2.00	-90.00	20.00	-8.00	2.50	-89.32
	Q25, Q75	1.00, 3.00	-94.12, -84.00	13.00, 25.00	-30.77, 12.90	1.00, 4.00	-94.88, -77.59
	Min, Max	0.0, 6.0	-100.0, -33.3	4.0, 36.0	-71.9, 113.3	0.0, 5.0	-100.0, 0.0
	Mean (SD)	2.27 (1.379)	-87.54 (11.101)	19.31 (7.892)	-4.19 (37.181)	2.42 (1.559)	-83.95 (20.041)
	95% CI of Mean	1.94, 2.59	-90.10, -84.98	16.60, 22.03	-16.97, 8.59	1.75, 3.08	-92.42, -75.48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 16:00 - 17:30	n	75	75	35	35	24	24
	Geometric Mean (CV%)	NC		19.68 (46.307)		NC	
	95% CI of Geometric Mean	NC		16.91, 22.91		NC	
	Median	2.00	-88.89	20.00	-4.35	2.00	-91.49
	Q25, Q75	2.00, 3.00	-93.55, -84.00	16.00, 27.00	-13.64, 7.69	1.00, 3.00	-94.24, -87.50
	Min, Max	0.0, 5.0	-100.0, 100.0	5.0, 44.0	-61.8, 80.0	0.0, 7.0	-100.0, -33.3
	Mean (SD)	2.31 (1.405)	-85.71 (23.372)	21.43 (8.494)	-3.58 (27.573)	2.13 (1.513)	-88.21 (13.358)
	95% CI of Mean	1.98, 2.63	-91.09, -80.33	18.51, 24.35	-13.06, 5.89	1.48, 2.77	-93.86, -82.57

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 20:00 - 21:30	n	75	75	35	35	24	24
	Geometric Mean (CV%)	NC		20.15 (52.772)		NC	
	95% CI of Geometric Mean	NC		16.99, 23.89		NC	
	Median	2.00	-90.48	21.00	-12.50	2.00	-90.91
	Q25, Q75	1.00, 3.00	-93.75, -84.62	17.00, 29.00	-28.21, 23.08	2.00, 3.00	-95.65, -87.23
	Min, Max	0.0, 7.0	-100.0, -50.0	3.0, 38.0	-45.0, 900.0	0.0, 5.0	-100.0, -33.3
	Mean (SD)	2.11 (1.352)	-88.55 (10.263)	22.14 (8.339)	23.13 (157.131)	2.25 (1.152)	-88.70 (12.993)
	95% CI of Mean	1.79, 2.42	-90.91, -86.18	19.27, 25.01	-30.85, 77.11	1.76, 2.74	-94.19, -83.20

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6, Discharge Confinement	n	75	75	35	35	24	24
	Geometric Mean (CV%)	NC		18.14 (37.432)		5.44 (50.723)	
	95% CI of Geometric Mean	NC		16.01, 20.55		4.44, 6.66	
	Median	7.00	-71.43	17.00	-12.90	5.50	-69.40
	Q25, Q75	5.00, 9.00	-80.00, -47.06	14.00, 24.00	-30.00, 23.81	4.00, 8.00	-83.95, -48.53
	Min, Max	0.0, 22.0	-100.0, 266.7	9.0, 38.0	-65.6, 200.0	2.0, 10.0	-93.1, 75.0
	Mean (SD)	6.88 (3.280)	-60.05 (43.873)	19.34 (7.207)	1.56 (49.000)	6.00 (2.503)	-59.03 (35.839)
	95% CI of Mean	6.12, 7.64	-70.15, -49.95	16.86, 21.82	-15.28, 18.40	4.94, 7.06	-74.17, -43.89

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline, Within 15 Min Prior To Smoking	n	40		34			
	Geometric Mean (CV%)	9.51 (65.798)		11.26 (38.053)			
	95% CI of Geometric Mean	7.84, 11.52		9.90, 12.81			
	Median	10.50		11.00			
	Q25, Q75	7.00, 15.00		10.00, 15.00			
	Min, Max	2.0, 27.0		4.0, 20.0			
	Mean (SD)	11.10 (5.879)		11.94 (3.798)			
	95% CI of Mean	9.22, 12.98		10.61, 13.27			

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline,	n					13	
08:00 - 09:30							
	Geometric Mean (CV%)					9.25 (34.640)	
	95% CI of Geometric Mean					7.54, 11.34	
	Median					10.00	
	Q25, Q75					8.00, 12.00	
	Min, Max					4.0, 15.0	
	Mean (SD)					9.69 (2.840)	
	95% CI of Mean					7.97, 11.41	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline, n		40		34		13	
12:00 - 13:30	Geometric Mean (CV%)	20.52 (64.312)		19.95 (51.843)		16.47 (74.431)	
	95% CI of Geometric Mean	17.00, 24.78		16.82, 23.65		11.02, 24.60	
	Median	21.00		21.00		22.00	
	Q25, Q75	16.50, 29.00		18.00, 27.00		10.00, 26.00	
	Min, Max	2.0, 51.0		3.0, 35.0		4.0, 39.0	
	Mean (SD)	23.50 (11.307)		21.74 (7.383)		19.62 (10.767)	
	95% CI of Mean	19.88, 27.12		19.15, 24.32		13.10, 26.13	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline, n		40		34		13	
16:00 - 17:30	Geometric Mean (CV%)	NC		21.08 (47.213)		18.90 (65.860)	
	95% CI of Geometric Mean	NC		18.02, 24.65		13.14, 27.17	
	Median	21.50		22.00		23.00	
	Q25, Q75	14.50, 30.00		19.00, 26.00		19.00, 25.00	
	Min, Max	0.0, 49.0		5.0, 43.0		3.0, 29.0	
	Mean (SD)	23.55 (11.675)		22.79 (7.981)		21.08 (7.124)	
	95% CI of Mean	19.81, 27.29		20.00, 25.58		16.77, 25.39	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline,	n	40		34		13	
20:00 - 21:30							
	Geometric Mean (CV%)	19.77 (70.763)		NC		20.24 (50.762)	
	95% CI of Geometric Mean	16.12, 24.24		NC		15.15, 27.04	
	Median	23.00		24.50		23.00	
	Q25, Q75	14.50, 30.00		18.00, 29.00		18.00, 29.00	
	Min, Max	2.0, 50.0		0.0, 47.0		6.0, 33.0	
	Mean (SD)	23.03 (11.139)		23.79 (10.036)		22.08 (8.129)	
	95% CI of Mean	19.46, 26.59		20.29, 27.30		17.16, 26.99	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	40	34	34	13	13
	Geometric Mean (CV%)	NC		17.67 (69.765)		NC	
	95% CI of Geometric Mean	NC		14.18, 22.01		NC	
	Median	3.00	-85.15	19.00	-6.57	3.00	-75.86
	Q25, Q75	2.00, 6.00	-94.00, -67.95	15.00, 27.00	-30.00, 32.00	1.00, 7.00	-97.44, -61.54
	Min, Max	0.0, 24.0	-100.0, 18.2	2.0, 43.0	-88.9, 122.2	0.0, 16.0	-100.0, 300.0
	Mean (SD)	4.85 (5.062)	-75.19 (27.030)	20.44 (9.520)	-0.36 (44.032)	4.77 (4.799)	-46.44 (107.496)
	95% CI of Mean	3.23, 6.47	-83.84, -66.54	17.11, 23.77	-15.72, 15.01	1.86, 7.67	-111.41, 18.52

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline, Within 15 Min Prior To Smoking	n	39		35			
	Geometric Mean (CV%)	9.48 (65.122)		10.94 (41.920)			
	95% CI of Geometric Mean	7.81, 11.50		9.52, 12.56			
	Median	10.00		11.00			
	Q25, Q75	6.00, 15.00		10.00, 15.00			
	Min, Max	2.0, 27.0		4.0, 20.0			
	Mean (SD)	11.05 (5.890)		11.71 (3.975)			
	95% CI of Mean	9.14, 12.97		10.34, 13.08			

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline,	n					12	
08:00 - 09:30							
	Geometric Mean (CV%)					8.75 (40.808)	
	95% CI of Geometric Mean					6.81, 11.23	
	Median					9.50	
	Q25, Q75					7.00, 12.00	
	Min, Max					4.0, 15.0	
	Mean (SD)					9.33 (3.257)	
	95% CI of Mean					7.26, 11.41	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline,	n	39		35		12	
12:00 - 13:30							
	Geometric Mean (CV%)	20.40 (63.545)		19.50 (53.191)		14.83 (69.288)	
	95% CI of Geometric Mean	16.89, 24.65		16.42, 23.15		9.96, 22.08	
	Median	21.00		21.00		16.50	
	Q25, Q75	15.00, 29.00		18.00, 27.00		10.00, 23.00	
	Min, Max	2.0, 51.0		3.0, 35.0		4.0, 39.0	
	Mean (SD)	23.33 (11.341)		21.37 (7.586)		17.42 (9.747)	
	95% CI of Mean	19.65, 27.01		18.76, 23.98		11.22, 23.61	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline,	n	39		35		12	
16:00 - 17:30							
	Geometric Mean (CV%)	NC		20.79 (47.311)		16.99 (69.783)	
	95% CI of Geometric Mean	NC		17.81, 24.26		11.38, 25.35	
	Median	21.00		22.00		20.00	
	Q25, Q75	14.00, 30.00		18.00, 26.00		14.00, 25.00	
	Min, Max	0.0, 49.0		5.0, 43.0		3.0, 29.0	
	Mean (SD)	23.03 (12.048)		22.51 (8.035)		19.33 (7.809)	
	95% CI of Mean	19.12, 26.94		19.75, 25.28		14.37, 24.30	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline,	n	39		35		12	
20:00 - 21:30							
	Geometric Mean (CV%)	19.57 (70.923)		NC		17.92 (57.324)	
	95% CI of Geometric Mean	15.91, 24.07		NC		12.77, 25.15	
	Median	22.00		24.00		22.00	
	Q25, Q75	14.00, 30.00		16.00, 29.00		13.50, 25.50	
	Min, Max	2.0, 50.0		0.0, 47.0		6.0, 33.0	
	Mean (SD)	22.82 (11.176)		23.49 (10.054)		20.00 (8.410)	
	95% CI of Mean	19.19, 26.45		20.03, 26.94		14.65, 25.35	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	35	35	12	12
	Geometric Mean (CV%)	NC		16.75 (63.136)		NC	
	95% CI of Geometric Mean	NC		13.72, 20.44		NC	
	Median	3.00	-90.00	18.00	-6.90	4.00	-72.44
	Q25, Q75	1.00, 6.00	-94.29, -74.07	11.00, 27.00	-33.33, 33.33	1.00, 13.00	-92.06, -24.04
	Min, Max	0.0, 29.0	-100.0, 26.1	4.0, 47.0	-71.9, 66.7	0.0, 23.0	-100.0, 475.0
	Mean (SD)	5.10 (6.932)	-76.19 (32.553)	19.34 (9.765)	-4.83 (39.363)	7.42 (8.785)	-20.32 (159.231)
	95% CI of Mean	2.85, 7.35	-86.75, -65.64	15.98, 22.70	-18.36, 8.70	1.83, 13.00	-121.50, 80.85

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline, Within 15 Min Prior To Smoking	n	47		32			
	Geometric Mean (CV%)	9.39 (61.731)		11.03 (40.186)			
	95% CI of Geometric Mean	7.94, 11.10		9.59, 12.69			
	Median	10.00		11.00			
	Q25, Q75	7.00, 15.00		10.00, 14.50			
	Min, Max	2.0, 27.0		4.0, 20.0			
	Mean (SD)	10.83 (5.605)		11.75 (3.819)			
	95% CI of Mean	9.18, 12.48		10.37, 13.13			

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline,	n					9	
08:00 - 09:30							
	Geometric Mean (CV%)					8.53 (42.706)	
	95% CI of Geometric Mean					6.22, 11.69	
	Median					10.00	
	Q25, Q75					7.00, 12.00	
	Min, Max					4.0, 12.0	
	Mean (SD)					9.11 (3.101)	
	95% CI of Mean					6.72, 11.50	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline,	n	47		32		9	
12:00 - 13:30							
	Geometric Mean (CV%)	20.29 (61.907)		20.26 (40.466)		14.53 (79.812)	
	95% CI of Geometric Mean	17.16, 23.99		17.60, 23.32		8.47, 24.93	
	Median	21.00		20.50		16.00	
	Q25, Q75	15.00, 29.00		18.00, 26.50		10.00, 23.00	
	Min, Max	2.0, 51.0		6.0, 35.0		4.0, 39.0	
	Mean (SD)	23.17 (11.347)		21.59 (7.062)		17.67 (10.944)	
	95% CI of Mean	19.83, 26.51		19.04, 24.14		9.25, 26.08	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline,	n	47		32		9	
16:00 - 17:30							
	Geometric Mean (CV%)	NC		21.55 (40.244)		17.03 (81.698)	
	95% CI of Geometric Mean	NC		18.73, 24.78		9.82, 29.51	
	Median	22.00		22.00		21.00	
	Q25, Q75	14.00, 30.00		18.50, 26.00		18.00, 25.00	
	Min, Max	0.0, 53.0		5.0, 43.0		3.0, 29.0	
	Mean (SD)	23.38 (12.144)		22.94 (7.650)		19.89 (8.448)	
	95% CI of Mean	19.81, 26.95		20.17, 25.70		13.39, 26.39	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline,	n	47		32		9	
20:00 - 21:30							
	Geometric Mean (CV%)	19.91 (67.408)		21.63 (47.160)		16.06 (60.647)	
	95% CI of Geometric Mean	16.63, 23.83		18.40, 25.43		10.44, 24.70	
	Median	23.00		24.50		21.00	
	Q25, Q75	15.00, 30.00		17.00, 28.50		11.00, 24.00	
	Min, Max	2.0, 50.0		5.0, 39.0		6.0, 29.0	
	Mean (SD)	23.02 (11.156)		23.50 (8.674)		18.11 (8.193)	
	95% CI of Mean	19.74, 26.30		20.37, 26.63		11.81, 24.41	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.



Table 15.2.4.6.1 Descriptive Statistics of Exhaled CO (ppm) - PP Set
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	Geometric Mean (CV%)	NC		16.99 (66.708)		3.35 (112.950)	
	95% CI of Geometric Mean	NC		13.65, 21.15		1.66, 6.73	
	Median	3.00	-81.82	19.00	-9.11	3.00	-80.00
	Q25, Q75	2.00, 8.00	-90.48, -61.54	14.00, 24.50	-30.85, 17.44	2.00, 7.00	-92.31, -63.64
	Min, Max	0.0, 25.0	-100.0, 8.7	2.0, 42.0	-93.8, 90.9	1.0, 15.0	-95.7, 275.0
	Mean (SD)	5.38 (5.195)	-72.67 (24.271)	19.47 (8.832)	-4.77 (40.600)	4.78 (4.438)	-35.50 (119.281)
	95% CI of Mean	3.85, 6.91	-79.80, -65.54	16.28, 22.66	-19.41, 9.87	1.36, 8.19	-127.19, 56.19

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline, Within 15 Min Prior To Smoking	n	79		41			
	Missing, n (%)	1(1.3)		0			
	Geometric Mean (CV%)	9.84 (52.991)		11.28 (41.798)			
	95% CI of Geometric Mean	8.80, 11.01		9.93, 12.81			
	Median	10.00		11.00			
	Q25, Q75	7.00, 14.00		10.00, 15.00			
	Min, Max	2.0, 27.0		4.0, 21.0			
	Mean (SD)	10.99 (4.963)		12.10 (4.212)			
	95% CI of Mean	9.87, 12.10		10.76, 13.43			

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline,	n					39	
08:00 - 09:30							
	Geometric Mean (CV%)					9.16 (53.006)	
	95% CI of Geometric Mean					7.79, 10.77	
	Median					11.00	
	Q25, Q75					7.00, 12.00	
	Min, Max					2.0, 21.0	
	Mean (SD)					10.15 (4.215)	
	95% CI of Mean					8.78, 11.53	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline,	n	79		41		39	
12:00 - 13:30							
	Missing, n (%)	1(1.3)		0		0	
	Geometric Mean (CV%)	19.85 (59.933)		20.93 (54.388)		19.75 (62.275)	
	95% CI of Geometric Mean	17.53, 22.47		17.82, 24.59		16.40, 23.78	
	Median	20.00		22.00		23.00	
	Q25, Q75	15.00, 29.00		19.00, 27.00		14.00, 29.00	
	Min, Max	2.0, 51.0		3.0, 47.0		4.0, 51.0	
	Mean (SD)	22.54 (10.801)		23.15 (9.259)		22.67 (11.089)	
	95% CI of Mean	20.12, 24.97		20.22, 26.07		19.07, 26.27	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline,	n	79		41		39	
16:00 - 17:30							
	Missing, n (%)	1(1.3)		0		0	
	Geometric Mean (CV%)	NC		22.71 (51.863)		22.13 (60.449)	
	95% CI of Geometric Mean	NC		19.46, 26.49		18.46, 26.53	
	Median	21.00		23.00		25.00	
	Q25, Q75	15.00, 30.00		19.00, 30.00		17.00, 29.00	
	Min, Max	0.0, 53.0		5.0, 55.0		3.0, 61.0	
	Mean (SD)	22.94 (10.725)		25.12 (10.900)		25.15 (12.133)	
	95% CI of Mean	20.53, 25.34		21.68, 28.57		21.22, 29.09	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline, 20:00 - 21:30	n	79		41		39	
	Missing, n (%)	1(1.3)		0		0	
	Geometric Mean (CV%)	21.26 (56.206)		NC		22.27 (79.051)	
	95% CI of Geometric Mean	18.90, 23.91		NC		17.76, 27.92	
	Median	23.00		26.00		25.00	
	Q25, Q75	16.00, 30.00		19.00, 33.00		19.00, 33.00	
	Min, Max	2.0, 53.0		0.0, 52.0		1.0, 48.0	
	Mean (SD)	23.73 (10.159)		25.78 (11.582)		26.03 (11.695)	
	95% CI of Mean	21.45, 26.01		22.12, 29.44		22.23, 29.82	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1, 12:00 - 13:30	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		16.91 (77.758)		7.36 (85.659)	
	95% CI of Geometric Mean	NC		13.60, 21.01		5.78, 9.37	
	Median	6.00	-71.43	20.00	-9.30	7.00	-64.29
	Q25, Q75	4.00, 8.00	-80.00, -63.64	12.00, 27.00	-33.33, 0.00	6.00, 10.00	-76.67, -39.13
	Min, Max	0.0, 24.0	-100.0, 33.3	2.0, 39.0	-75.0, 63.2	1.0, 33.0	-92.3, 25.0
	Mean (SD)	6.33 (3.741)	-68.05 (21.777)	20.17 (10.097)	-12.12 (34.179)	9.46 (7.448)	-53.60 (31.251)
	95% CI of Mean	5.49, 7.17	-72.93, -63.17	16.98, 23.36	-22.91, -1.33	7.04, 11.88	-63.74, -43.47

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1, 16:00 - 17:30	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		19.36 (74.883)		5.01 (99.759)	
	95% CI of Geometric Mean	NC		15.68, 23.91		3.82, 6.56	
	Median	4.00	-81.58	21.00	-15.00	5.00	-78.57
	Q25, Q75	3.00, 6.00	-86.84, -71.43	14.00, 29.00	-25.81, 10.53	3.00, 7.00	-84.62, -63.64
	Min, Max	0.0, 12.0	-100.0, 200.0	1.0, 44.0	-80.0, 65.2	1.0, 46.0	-95.0, 0.0
	Mean (SD)	4.38 (2.295)	-75.67 (33.837)	22.54 (10.517)	-9.35 (28.880)	7.46 (9.277)	-69.25 (27.051)
	95% CI of Mean	3.86, 4.90	-83.25, -68.09	19.21, 25.86	-18.47, -0.23	4.45, 10.47	-78.02, -60.47

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1, 20:00 - 21:30	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		20.46 (60.813)		NC	
	95% CI of Geometric Mean	NC		17.14, 24.43		NC	
	Median	3.00	-86.84	23.00	-10.26	3.00	-84.85
	Q25, Q75	2.00, 4.00	-90.91, -78.95	17.00, 29.00	-25.00, 14.29	3.00, 5.00	-89.66, -75.00
	Min, Max	0.0, 8.0	-100.0, -61.1	3.0, 40.0	-71.4, 300.0	0.0, 43.0	-100.0, 200.0
	Mean (SD)	3.23 (1.895)	-85.08 (9.741)	22.98 (9.162)	1.59 (56.511)	6.38 (9.627)	-68.08 (52.048)
	95% CI of Mean	2.80, 3.66	-87.27, -82.90	20.08, 25.87	-16.25, 19.44	3.26, 9.51	-84.96, -51.21

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2, Within 15 Min Prior To Smoking	n	79	79	41	41		
	Missing, n (%)	1(1.3)	1(1.3)	0	0		
	Geometric Mean (CV%)	NC		10.13 (49.213)			
	95% CI of Geometric Mean	NC		8.74, 11.74			
	Median	3.00	-76.92	11.00	-7.14		
	Q25, Q75	2.00, 3.00	-84.62, -66.67	9.00, 14.00	-21.43, 6.67		
	Min, Max	0.0, 13.0	-100.0, 44.4	2.0, 21.0	-69.2, 50.0		
	Mean (SD)	2.62 (1.697)	-72.23 (22.235)	11.05 (4.068)	-6.52 (24.975)		
	95% CI of Mean	2.24, 3.01	-77.21, -67.24	9.76, 12.34	-14.41, 1.37		

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2, 08:00 - 09:30	n					39	39
	Geometric Mean (CV%)					3.21 (76.853)	
	95% CI of Geometric Mean					2.57, 4.00	
	Median					3.00	-70.00
	Q25, Q75					2.00, 4.00	-75.00, -50.00
	Min, Max					1.0, 21.0	-86.7, 0.0
	Mean (SD)					4.31 (4.584)	-58.23 (26.902)
	95% CI of Mean					2.82, 5.80	-66.96, -49.51

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2, 12:00 - 13:30	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		16.50 (61.332)		NC	
	95% CI of Geometric Mean	NC		13.80, 19.73		NC	
	Median	2.00	-90.00	18.00	-20.00	3.00	-87.50
	Q25, Q75	2.00, 3.00	-93.75, -83.33	11.00, 25.00	-38.46, 0.00	2.00, 4.00	-92.31, -64.29
	Min, Max	0.0, 5.0	-100.0, 66.7	3.0, 37.0	-68.8, 66.7	0.0, 33.0	-100.0, 30.0
	Mean (SD)	2.34 (1.358)	-85.88 (19.790)	18.90 (9.127)	-14.94 (33.185)	6.03 (8.789)	-71.59 (34.297)
	95% CI of Mean	2.03, 2.65	-90.32, -81.44	16.02, 21.79	-25.42, -4.46	3.17, 8.88	-82.71, -60.47

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2, 16:00 - 17:30	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		19.69 (53.965)		NC	
	95% CI of Geometric Mean	NC		16.78, 23.10		NC	
	Median	3.00	-88.89	22.00	-12.50	3.00	-88.46
	Q25, Q75	1.00, 3.00	-94.59, -83.33	15.00, 27.00	-25.81, 5.56	2.00, 4.00	-92.31, -75.00
	Min, Max	0.0, 5.0	-100.0, 0.0	4.0, 44.0	-64.7, 68.4	0.0, 46.0	-100.0, 0.0
	Mean (SD)	2.37 (1.342)	-86.25 (14.611)	21.85 (9.219)	-9.28 (27.224)	5.79 (9.718)	-75.74 (30.620)
	95% CI of Mean	2.06, 2.67	-89.53, -82.97	18.94, 24.77	-17.88, -0.68	2.64, 8.95	-85.67, -65.81

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2, 20:00 - 21:30	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		21.31 (56.289)		NC	
	95% CI of Geometric Mean	NC		18.06, 25.16		NC	
	Median	2.00	-90.00	24.00	-6.25	2.00	-89.66
	Q25, Q75	1.00, 3.00	-95.74, -85.00	17.00, 30.00	-24.14, 14.29	1.00, 3.00	-96.00, -84.21
	Min, Max	0.0, 6.0	-100.0, -50.0	4.0, 48.0	-60.0, 400.0	0.0, 43.0	-100.0, 100.0
	Mean (SD)	2.19 (1.388)	-89.27 (9.021)	23.78 (9.848)	6.87 (69.386)	5.05 (10.021)	-76.38 (40.793)
	95% CI of Mean	1.87, 2.51	-91.29, -87.24	20.67, 26.89	-15.04, 28.77	1.80, 8.30	-89.61, -63.15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3, Within 15 Min Prior To Smoking	n	79	79	41	41		
	Missing, n (%)	1(1.3)	1(1.3)	0	0		
	Geometric Mean (CV%)	NC		10.29 (48.107)			
	95% CI of Geometric Mean	NC		8.90, 11.89			
	Median	2.00	-80.00	10.00	-10.00		
	Q25, Q75	1.00, 3.00	-84.62, -70.00	8.00, 15.00	-18.18, 0.00		
	Min, Max	0.0, 5.0	-100.0, 0.0	3.0, 21.0	-44.4, 60.0		
	Mean (SD)	2.18 (1.010)	-76.10 (16.321)	11.24 (4.364)	-6.80 (20.324)		
	95% CI of Mean	1.95, 2.41	-79.76, -72.44	9.86, 12.63	-13.22, -0.38		

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3, 08:00 - 09:30	n					39	39
	Geometric Mean (CV%)					NC	
	95% CI of Geometric Mean					NC	
	Median					2.00	-72.73
	Q25, Q75					2.00, 3.00	-80.00, -50.00
	Min, Max					0.0, 21.0	-100.0, 0.0
	Mean (SD)					3.97 (4.722)	-61.67 (28.617)
	95% CI of Mean					2.44, 5.51	-70.95, -52.39

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3, 12:00 - 13:30	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		16.63 (66.212)		NC	
	95% CI of Geometric Mean	NC		13.74, 20.12		NC	
	Median	2.00	-90.00	19.00	-20.00	3.00	-86.21
	Q25, Q75	1.00, 3.00	-93.75, -80.00	12.00, 27.00	-34.78, 4.55	2.00, 5.00	-94.12, -70.00
	Min, Max	0.0, 6.0	-100.0, 0.0	3.0, 34.0	-75.0, 66.7	0.0, 33.0	-100.0, 0.0
	Mean (SD)	2.44 (1.357)	-85.47 (14.760)	19.22 (8.966)	-14.37 (32.396)	5.51 (8.153)	-75.55 (28.833)
	95% CI of Mean	2.13, 2.75	-88.78, -82.15	16.38, 22.05	-24.60, -4.14	2.87, 8.16	-84.90, -66.20

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3, 16:00 - 17:30	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		20.68 (53.346)		2.99 (121.269)	
	95% CI of Geometric Mean	NC		17.66, 24.23		2.19, 4.08	
	Median	3.00	-87.88	23.00	0.00	3.00	-85.71
	Q25, Q75	1.00, 3.00	-94.34, -81.25	17.00, 28.00	-24.53, 15.79	2.00, 4.00	-92.31, -81.25
	Min, Max	0.0, 6.0	-100.0, 100.0	4.0, 44.0	-64.7, 68.8	1.0, 46.0	-97.8, 0.0
	Mean (SD)	2.54 (1.395)	-83.87 (23.827)	22.90 (9.383)	-3.16 (32.947)	5.62 (9.708)	-76.92 (28.838)
	95% CI of Mean	2.23, 2.86	-89.21, -78.53	19.94, 25.87	-13.57, 7.24	2.46, 8.77	-86.28, -67.57

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3, 20:00 - 21:30	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		21.89 (46.263)		NC	
	95% CI of Geometric Mean	NC		19.04, 25.16		NC	
	Median	2.00	-90.91	22.00	-8.70	3.00	-87.50
	Q25, Q75	1.00, 3.00	-94.44, -84.62	18.00, 30.00	-25.93, 10.26	2.00, 4.00	-92.00, -77.78
	Min, Max	0.0, 7.0	-100.0, -57.1	5.0, 43.0	-39.3, 900.0	0.0, 43.0	-100.0, 300.0
	Mean (SD)	2.30 (1.514)	-88.97 (8.556)	23.78 (9.057)	19.93 (144.896)	5.87 (9.796)	-68.05 (66.750)
	95% CI of Mean	1.96, 2.65	-90.89, -87.05	20.92, 26.64	-25.81, 65.67	2.69, 9.05	-89.70, -46.41

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4, Within 15 Min Prior To Smoking	n	79	79	41	41		
	Missing, n (%)	1(1.3)	1(1.3)	0	0		
	Geometric Mean (CV%)	NC		10.46 (49.015)			
	95% CI of Geometric Mean	NC		9.03, 12.11			
	Median	2.00	-80.00	12.00	-9.09		
	Q25, Q75	1.00, 3.00	-88.89, -71.43	9.00, 14.00	-20.00, 9.09		
	Min, Max	0.0, 7.0	-100.0, -28.6	2.0, 21.0	-60.0, 160.0		
	Mean (SD)	2.11 (1.291)	-78.09 (14.338)	11.39 (4.117)	-2.27 (35.973)		
	95% CI of Mean	1.82, 2.41	-81.30, -74.87	10.09, 12.69	-13.63, 9.09		

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4, 08:00 - 09:30	n					39	39
	Geometric Mean (CV%)					2.82 (87.648)	
	95% CI of Geometric Mean					2.20, 3.60	
	Median					2.00	-71.43
	Q25, Q75					2.00, 4.00	-80.00, -50.00
	Min, Max					1.0, 21.0	-92.9, 0.0
	Mean (SD)					4.03 (4.688)	-61.65 (27.434)
	95% CI of Mean					2.50, 5.55	-70.55, -52.75

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4, 12:00 - 13:30	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		16.99 (67.129)		NC	
	95% CI of Geometric Mean	NC		14.01, 20.60		NC	
	Median	3.00	-89.80	19.00	-20.00	3.00	-88.46
	Q25, Q75	2.00, 3.00	-93.62, -83.33	13.00, 25.00	-30.43, 0.00	2.00, 4.00	-92.59, -70.59
	Min, Max	0.0, 9.0	-100.0, 66.7	1.0, 37.0	-83.3, 133.3	0.0, 33.0	-100.0, 0.0
	Mean (SD)	2.58 (1.623)	-83.79 (22.513)	19.27 (8.103)	-11.97 (36.252)	5.41 (8.137)	-74.72 (29.688)
	95% CI of Mean	2.21, 2.95	-88.84, -78.74	16.71, 21.83	-23.41, -0.52	2.77, 8.05	-84.35, -65.09

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4, 16:00 - 17:30	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		20.56 (49.430)		NC	
	95% CI of Geometric Mean	NC		17.74, 23.84		NC	
	Median	2.00	-88.89	22.00	-6.45	3.00	-88.24
	Q25, Q75	2.00, 3.00	-93.75, -81.25	16.00, 28.00	-20.69, 10.53	2.00, 3.00	-92.59, -77.78
	Min, Max	0.0, 9.0	-100.0, 100.0	5.0, 44.0	-68.0, 106.3	0.0, 46.0	-100.0, 0.0
	Mean (SD)	2.49 (1.625)	-84.06 (24.048)	22.59 (9.201)	-4.10 (32.311)	5.62 (9.722)	-77.02 (28.941)
	95% CI of Mean	2.12, 2.86	-89.45, -78.67	19.68, 25.49	-14.31, 6.10	2.46, 8.77	-86.41, -67.64

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4, 20:00 - 21:30	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		22.27 (47.952)		NC	
	95% CI of Geometric Mean	NC		19.29, 25.72		NC	
	Median	2.00	-90.91	25.00	0.00	2.00	-89.47
	Q25, Q75	1.00, 3.00	-96.00, -85.71	18.00, 30.00	-21.74, 23.08	1.00, 3.00	-93.75, -84.21
	Min, Max	0.0, 6.0	-100.0, -50.0	6.0, 41.0	-65.0, 600.0	0.0, 43.0	-100.0, 0.0
	Mean (SD)	2.06 (1.427)	-89.42 (9.590)	24.29 (9.136)	16.29 (99.441)	5.28 (9.953)	-76.68 (33.550)
	95% CI of Mean	1.74, 2.39	-91.57, -87.27	21.40, 27.18	-15.10, 47.69	2.05, 8.51	-87.56, -65.80

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, Within 15 Min Prior To Smoking	n	79	79	41	41		
	Missing, n (%)	1(1.3)	1(1.3)	0	0		
	Geometric Mean (CV%)	NC		10.77 (49.234)			
	95% CI of Geometric Mean	NC		9.29, 12.48			
	Median	2.00	-77.78	12.00	-8.33		
	Q25, Q75	2.00, 3.00	-84.62, -69.23	9.00, 15.00	-16.67, 11.76		
	Min, Max	0.0, 6.0	-100.0, -25.0	3.0, 21.0	-58.3, 160.0		
	Mean (SD)	2.44 (1.118)	-74.51 (14.326)	11.76 (4.306)	0.34 (35.149)		
	95% CI of Mean	2.19, 2.70	-77.73, -71.30	10.39, 13.12	-10.76, 11.44		

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 08:00 - 09:30	n					39	39
	Geometric Mean (CV%)					NC	
	95% CI of Geometric Mean					NC	
	Median					2.00	-72.73
	Q25, Q75					2.00, 4.00	-81.82, -50.00
	Min, Max					0.0, 21.0	-100.0, 0.0
	Mean (SD)					4.00 (4.697)	-62.36 (28.785)
	95% CI of Mean					2.47, 5.53	-71.69, -53.02

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 12:00 - 13:30	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		18.74 (53.033)		NC	
	95% CI of Geometric Mean	NC		16.01, 21.93		NC	
	Median	2.00	-90.00	20.00	-8.00	3.00	-88.89
	Q25, Q75	2.00, 3.00	-94.12, -83.33	14.00, 26.00	-30.00, 12.90	1.00, 4.00	-94.12, -75.00
	Min, Max	0.0, 6.0	-100.0, -33.3	4.0, 41.0	-71.9, 113.3	0.0, 33.0	-100.0, 0.0
	Mean (SD)	2.30 (1.363)	-87.19 (11.398)	20.78 (8.639)	-4.46 (35.597)	5.23 (8.219)	-76.01 (30.977)
	95% CI of Mean	1.99, 2.61	-89.75, -84.63	18.05, 23.51	-15.70, 6.78	2.56, 7.90	-86.06, -65.97

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 16:00 - 17:30	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		20.94 (46.103)		NC	
	95% CI of Geometric Mean	NC		18.23, 24.06		NC	
	Median	2.00	-88.89	21.00	-5.56	2.00	-90.91
	Q25, Q75	2.00, 3.00	-93.55, -84.00	18.00, 29.00	-18.60, 7.69	1.00, 3.00	-93.75, -84.21
	Min, Max	0.0, 6.0	-100.0, 100.0	5.0, 44.0	-61.8, 80.0	0.0, 46.0	-100.0, 0.0
	Mean (SD)	2.34 (1.467)	-85.88 (22.823)	22.76 (8.700)	-3.43 (29.440)	5.21 (9.879)	-79.52 (29.584)
	95% CI of Mean	2.01, 2.68	-90.99, -80.76	20.01, 25.51	-12.72, 5.87	2.00, 8.41	-89.12, -69.93

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5, 20:00 - 21:30	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		21.35 (51.017)		NC	
	95% CI of Geometric Mean	NC		18.34, 24.85		NC	
	Median	2.00	-90.48	26.00	-12.50	2.00	-89.47
	Q25, Q75	1.00, 3.00	-93.75, -85.29	17.00, 29.00	-28.21, 13.04	2.00, 3.00	-95.56, -85.71
	Min, Max	0.0, 7.0	-100.0, -50.0	3.0, 38.0	-45.0, 900.0	0.0, 43.0	-100.0, 100.0
	Mean (SD)	2.15 (1.360)	-88.63 (10.030)	23.32 (8.332)	18.30 (145.711)	5.31 (9.930)	-75.13 (41.140)
	95% CI of Mean	1.84, 2.46	-90.88, -86.38	20.68, 25.95	-27.70, 64.30	2.08, 8.53	-88.47, -61.79

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6, Discharge Confinement	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		19.06 (39.109)		7.02 (79.287)	
	95% CI of Geometric Mean	NC		16.92, 21.48		5.59, 8.80	
	Median	7.00	-71.43	18.00	-15.00	7.00	-60.87
	Q25, Q75	5.00, 9.00	-79.31, -47.06	15.00, 25.00	-26.67, 22.22	4.00, 11.00	-80.49, -37.50
	Min, Max	0.0, 22.0	-100.0, 266.7	9.0, 41.0	-65.6, 200.0	2.0, 33.0	-93.1, 75.0
	Mean (SD)	6.94 (3.264)	-60.02 (42.948)	20.44 (7.925)	-0.91 (46.517)	9.03 (7.408)	-52.78 (35.843)
	95% CI of Mean	6.20, 7.67	-69.64, -50.39	17.93, 22.95	-15.60, 13.78	6.62, 11.43	-64.40, -41.15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		18.56 (67.542)		NC	
	95% CI of Geometric Mean	NC		15.29, 22.52		NC	
	Median	4.00	-75.00	19.00	-6.25	7.00	-68.29
	Q25, Q75	2.00, 10.00	-90.91, -46.15	15.00, 27.00	-25.58, 18.75	2.00, 13.00	-87.50, -29.41
	Min, Max	0.0, 27.0	-100.0, 100.0	2.0, 48.0	-88.9, 122.2	0.0, 33.0	-100.0, 300.0
	Mean (SD)	6.39 (5.583)	-66.06 (33.273)	21.39 (10.060)	-1.15 (41.886)	9.59 (9.179)	-49.85 (65.783)
	95% CI of Mean	5.14, 7.65	-73.52, -58.60	18.21, 24.57	-14.38, 12.07	6.61, 12.57	-71.18, -28.52

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		17.81 (60.700)		NC	
	95% CI of Geometric Mean	NC		14.92, 21.26		NC	
	Median	5.00	-82.76	21.00	-7.69	8.00	-60.00
	Q25, Q75	2.00, 10.00	-90.91, -47.73	12.00, 27.00	-28.57, 32.00	4.00, 15.00	-81.82, -23.08
	Min, Max	0.0, 29.0	-100.0, 26.1	4.0, 47.0	-71.9, 66.7	0.0, 33.0	-100.0, 475.0
	Mean (SD)	6.85 (7.030)	-66.15 (34.259)	20.32 (9.510)	-6.27 (38.122)	10.74 (8.870)	-38.83 (90.725)
	95% CI of Mean	5.27, 8.43	-73.83, -58.47	17.31, 23.32	-18.31, 5.77	7.86, 13.62	-68.24, -9.41

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.6.2 Descriptive Statistics of Exhaled CO (ppm) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	79	79	41	41	39	39
	Missing, n (%)	1(1.3)	1(1.3)	0	0	0	0
	Geometric Mean (CV%)	NC		18.07 (68.631)		NC	
	95% CI of Geometric Mean	NC		14.85, 21.99		NC	
	Median	5.00	-73.33	21.00	-7.41	9.00	-59.26
	Q25, Q75	2.00, 10.00	-90.00, -45.00	15.00, 27.00	-25.58, 16.13	4.00, 15.00	-80.49, -12.50
	Min, Max	0.0, 25.0	-100.0, 8.7	2.0, 42.0	-93.8, 90.9	0.0, 33.0	-100.0, 275.0
	Mean (SD)	6.67 (5.875)	-66.08 (26.727)	20.78 (9.063)	-4.08 (37.352)	11.33 (9.320)	-40.50 (63.762)
	95% CI of Mean	5.35, 7.99	-72.07, -60.09	17.92, 23.65	-15.87, 7.71	8.31, 14.36	-61.17, -19.82

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: For patients randomized to SA, if the 08:00 - 09:30 Day 1 measurement was missing then the latest non-missing measurement within 15 minutes prior to smoking on Day -1 or Day 0 was used.

Note: NC = Not Calculated.

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set****Parameter (units): Total 1-OHP (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		30		22	
	Missing, n (%)	10 (13.3)		5 (14.3)		2 (8.3)	
	Geometric Mean (CV%)	146.56 (62.664)		139.92 (67.809)		107.62 (56.181)	
	95% CI of Geometric Mean	127.08, 169.03		111.20, 176.05		85.31, 135.76	
	Median	146.85		146.95		101.57	
	Q25, Q75	106.37, 207.97		86.30, 231.21		76.04, 149.83	
	Min, Max	27.7, 841.5		29.8, 386.7		47.1, 284.2	
	Mean (SD)	172.60 (115.363)		165.50 (93.488)		123.04 (68.084)	
	95% CI of Mean	144.01, 201.19		130.59, 200.42		92.85, 153.23	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set****Parameter (units): Total 1-OHP (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	71	65	33	30	22	22
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	2 (8.3)
	Geometric Mean (CV%)	99.00 (57.473)		144.48 (75.404)		77.27 (61.360)	
	95% CI of Geometric Mean	87.24, 112.35		113.88, 183.29		60.14, 99.28	
	Median	95.22	-35.70	155.14	-7.58	80.85	-30.00
	Q25, Q75	66.33, 156.95	-43.05, -21.43	80.29, 255.95	-17.75, 11.09	50.85, 110.59	-38.99, -17.68
	Min, Max	21.3, 312.9	-75.1, 106.0	45.9, 559.3	-45.2, 178.1	25.5, 212.0	-62.6, 83.6
	Mean (SD)	113.59 (61.014)	-28.95 (28.368)	178.60 (119.009)	1.82 (40.102)	89.60 (50.280)	-24.38 (28.807)
	95% CI of Mean	99.14, 128.03	-35.99, -21.92	136.40, 220.80	-13.16, 16.79	67.30, 111.89	-37.15, -11.60

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set****Parameter (units): Total 1-OHP (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	71	65	33	30	22	22
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	2 (8.3)
	Geometric Mean (CV%)	92.61 (62.495)		144.90 (65.448)		73.68 (49.455)	
	95% CI of Geometric Mean	80.83, 106.10		117.25, 179.07		59.87, 90.66	
	Median	92.51	-34.54	165.10	-3.06	77.53	-38.57
	Q25, Q75	62.68, 134.87	-50.52, -12.00	84.66, 233.49	-8.44, 13.74	51.80, 103.22	-42.17, -14.86
	Min, Max	16.8, 318.0	-84.5, 58.4	42.1, 343.4	-39.6, 89.4	33.7, 192.6	-70.4, 73.4
	Mean (SD)	108.48 (64.226)	-30.68 (28.522)	169.30 (87.849)	3.33 (29.606)	81.89 (40.468)	-24.53 (37.277)
	95% CI of Mean	93.27, 123.69	-37.76, -23.61	138.15, 200.46	-7.73, 14.39	63.94, 99.83	-41.07, -8.00

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set****Parameter (units): Total 1-OHP (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	71	65	33	30	22	22
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	2 (8.3)
	Geometric Mean (CV%)	78.32 (53.608)		140.72 (59.195)		61.51 (55.504)	
	95% CI of Geometric Mean	69.53, 88.22		115.86, 170.91		48.88, 77.40	
	Median	76.95	-44.23	146.30	-2.52	66.52	-39.46
	Q25, Q75	56.86, 117.28	-55.59, -31.26	93.67, 210.27	-19.22, 11.52	37.48, 85.07	-48.07, -31.26
	Min, Max	15.4, 297.8	-83.5, 15.4	48.6, 365.0	-45.6, 63.2	24.1, 154.9	-70.5, -8.5
	Mean (SD)	88.61 (47.378)	-43.14 (18.331)	161.64 (84.142)	-1.49 (21.465)	69.51 (34.579)	-40.71 (15.391)
	95% CI of Mean	77.39, 99.83	-47.69, -38.60	131.80, 191.48	-9.51, 6.53	54.17, 84.84	-47.54, -33.88

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set****Parameter (units): Total 1-OHP (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	71	65	33	30	22	22
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	2 (8.3)
	Geometric Mean (CV%)	72.65 (52.692)		134.63 (59.646)		54.23 (61.020)	
	95% CI of Geometric Mean	64.61, 81.68		110.70, 163.72		42.25, 69.60	
	Median	71.22	-48.41	158.96	-8.84	55.53	-48.12
	Q25, Q75	50.95, 102.48	-60.06, -34.19	78.05, 215.11	-17.32, 8.97	36.11, 79.67	-61.49, -31.50
	Min, Max	17.7, 272.0	-86.8, -16.1	47.0, 327.9	-44.4, 57.9	18.1, 146.2	-79.5, -2.5
	Mean (SD)	81.86 (42.993)	-47.29 (16.998)	154.42 (77.574)	-4.70 (21.844)	62.85 (35.801)	-46.25 (19.510)
	95% CI of Mean	71.68, 92.04	-51.50, -43.07	126.90, 181.93	-12.86, 3.47	46.97, 78.73	-54.91, -37.60

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set****Parameter (units): Total 1-OHP (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	71	65	33	30	22	22
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	2 (8.3)
	BLOQ, n(%)	2 (2.8)		0		0	
	Geometric Mean (CV%)	64.87 (53.955)		135.14 (59.655)		47.80 (75.567)	
	95% CI of Geometric Mean	57.55, 73.12		111.12, 164.35		35.48, 64.40	
	Median	71.91	-53.74	141.08	-5.55	46.25	-53.91
	Q25, Q75	46.39, 96.26	-63.80, -45.62	80.02, 209.05	-17.51, 7.64	31.04, 76.59	-68.75, -40.19
	Min, Max	10.0, 220.1	-89.0, 13.6	47.9, 327.8	-50.2, 60.8	11.9, 182.9	-74.6, -19.3
	Mean (SD)	72.90 (35.635)	-53.41 (16.847)	155.49 (80.671)	-4.82 (23.036)	59.27 (42.355)	-53.14 (15.375)
	95% CI of Mean	64.46, 81.34	-57.59, -49.23	126.88, 184.10	-13.43, 3.79	40.48, 78.05	-59.96, -46.32

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set****Parameter (units): Total 1-OHP (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	36		29		13	
	Missing, n (%)	4 (10.0)		5 (14.7)		0	
	Geometric Mean (CV%)	162.93 (58.570)		135.61 (72.450)		119.14 (53.804)	
	95% CI of Geometric Mean	135.57, 195.80		105.92, 173.62		87.84, 161.59	
	Median	152.44		145.15		122.39	
	Q25, Q75	121.15, 208.51		86.30, 231.21		81.00, 167.14	
	Min, Max	47.0, 841.5		29.8, 386.7		56.7, 259.7	
	Mean (SD)	190.93 (136.470)		163.33 (96.406)		133.56 (65.611)	
	95% CI of Mean	144.75, 237.11		126.65, 200.01		93.91, 173.21	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set****Parameter (units): Total 1-OHP (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	39	36	32	29	13	13
	Missing, n (%)	1 (2.5)	4 (10.0)	2 (5.9)	5 (14.7)	0	
	Geometric Mean (CV%)	110.67 (62.048)		173.68 (72.510)		106.74 (81.998)	
	95% CI of Geometric Mean	91.97, 133.16		137.39, 219.55		69.20, 164.65	
	Median	110.74	-36.35	189.70	17.41	106.09	-21.20
	Q25, Q75	71.26, 154.78	-53.02, -1.02	120.39, 263.03	-2.91, 30.10	85.74, 120.72	-46.76, 7.67
	Min, Max	39.4, 547.7	-91.5, 94.3	51.7, 739.8	-40.0, 391.5	35.6, 396.6	-59.1, 219.8
	Mean (SD)	131.54 (92.634)	-24.10 (42.654)	211.29 (141.075)	37.49 (83.606)	137.95 (117.520)	12.84 (87.999)
	95% CI of Mean	101.50, 161.57	-38.54, -9.66	160.42, 262.15	5.68, 69.30	66.93, 208.97	-40.35, 66.02

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set****Parameter (units): Total 1-OHP (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	35		30		11	
	Missing, n (%)	4 (10.3)		5 (14.3)		1 (8.3)	
	Geometric Mean (CV%)	148.95 (58.364)		133.44 (71.735)		100.89 (43.636)	
	95% CI of Geometric Mean	123.67, 179.41		104.90, 169.74		76.21, 133.56	
	Median	143.92		138.92		101.77	
	Q25, Q75	109.36, 195.16		83.69, 231.21		67.60, 128.53	
	Min, Max	47.0, 841.5		29.8, 386.7		56.7, 226.8	
	Mean (SD)	175.48 (134.612)		160.67 (95.839)		109.44 (48.782)	
	95% CI of Mean	129.24, 221.73		124.88, 196.47		76.67, 142.22	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set****Parameter (units): Total 1-OHP (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	35	33	30	11	11
	Missing, n (%)	0	4 (10.3)	2 (5.7)	5 (14.3)	1 (8.3)	1 (8.3)
	Geometric Mean (CV%)	103.84 (66.737)		166.40 (70.416)		94.00 (72.345)	
	95% CI of Geometric Mean	85.29, 126.43		132.87, 208.40		60.79, 145.36	
	Median	100.00	-29.10	154.48	14.13	98.96	-19.73
	Q25, Q75	73.41, 133.11	-55.12, -2.09	105.74, 260.65	-8.10, 42.74	55.70, 176.25	-34.98, 24.46
	Min, Max	32.3, 872.6	-90.8, 51.0	43.2, 493.2	-66.0, 649.2	27.6, 210.0	-54.5, 256.0
	Mean (SD)	131.02 (136.621)	-24.54 (36.258)	200.43 (122.454)	41.75 (125.219)	111.48 (62.753)	11.81 (87.118)
	95% CI of Mean	86.73, 175.32	-37.00, -12.08	157.01, 243.86	-5.01, 88.51	69.31, 153.64	-46.72, 70.34

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set****Parameter (units): Total 1-OHP (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	43		29		9	
	Missing, n (%)	4 (8.5)		3 (9.4)		0	
	Geometric Mean (CV%)	160.27 (57.772)		129.15 (69.781)		90.25 (35.270)	
	95% CI of Geometric Mean	135.86, 189.05		101.63, 164.12		69.36, 117.43	
	Median	151.21		132.69		98.45	
	Q25, Q75	116.41, 209.04		83.69, 198.63		67.60, 115.46	
	Min, Max	47.0, 841.5		29.8, 386.7		56.7, 146.5	
	Mean (SD)	186.75 (128.653)		154.33 (90.906)		94.97 (31.583)	
	95% CI of Mean	147.16, 226.35		119.75, 188.92		70.69, 119.25	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set****Parameter (units): Total 1-OHP (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	43	32	29	9	9
	Missing, n (%)	0	4 (8.5)	0	3 (9.4)	0	
	Geometric Mean (CV%)	117.77 (67.181)		163.80 (63.703)		70.19 (45.705)	
	95% CI of Geometric Mean	98.44, 140.89		132.71, 202.16		50.22, 98.11	
	Median	112.84	-20.03	162.58	18.43	56.65	-19.04
	Q25, Q75	87.11, 165.68	-47.19, 12.31	111.77, 272.71	2.42, 39.80	54.24, 102.05	-23.06, -4.99
	Min, Max	33.9, 387.6	-89.4, 105.5	50.7, 386.3	-32.6, 116.7	40.3, 139.2	-50.9, 0.3
	Mean (SD)	141.02 (88.768)	-14.61 (45.578)	190.63 (100.960)	26.54 (40.965)	76.45 (34.011)	-19.83 (19.189)
	95% CI of Mean	114.95, 167.09	-28.64, -0.58	154.22, 227.03	10.95, 42.13	50.30, 102.60	-34.58, -5.07

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set**

Parameter (units): Total 1-OHP (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	66	30	22
	Missing, n (%)	9 (12.0)	5 (14.3)	2 (8.3)
	Geometric Mean (CV%)	241.32 (56.502)	221.82 (53.742)	174.42 (45.827)
	95% CI of Geometric Mean	212.03, 274.66	183.78, 267.73	143.72, 211.68
	Median	257.90	200.64	173.14
	Q25, Q75	196.79, 357.86	159.32, 360.13	130.70, 208.43
	Min, Max	51.9, 947.7	65.9, 493.9	74.5, 420.5
	Mean (SD)	274.12 (143.803)	249.25 (119.120)	191.27 (88.420)
	95% CI of Mean	238.76, 309.48	204.77, 293.74	152.06, 230.47

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set**

Parameter (units): Total 1-OHP (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	Geometric Mean (CV%)	162.17 (51.702)	232.70 (59.854)	124.81 (49.568)
	95% CI of Geometric Mean	144.52, 181.98	191.24, 283.15	101.38, 153.64
	Median	157.29	235.64	104.83
	Q25, Q75	117.29, 221.71	153.14, 369.40	88.24, 171.05
	Min, Max	43.1, 501.6	90.2, 663.0	50.9, 275.5
	Mean (SD)	182.52 (95.548)	268.55 (145.248)	138.56 (65.989)
	95% CI of Mean	159.89, 205.14	217.04, 320.06	109.30, 167.82

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set**

Parameter (units): Total 1-OHP (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	Geometric Mean (CV%)	152.05 (58.968)	236.87 (54.285)	119.66 (47.235)
	95% CI of Geometric Mean	133.61, 173.05	197.80, 283.64	98.07, 146.01
	Median	154.13	261.74	117.00
	Q25, Q75	113.29, 213.24	166.80, 313.31	81.17, 152.20
	Min, Max	34.3, 495.3	85.6, 571.6	62.5, 316.2
	Mean (SD)	175.88 (101.194)	265.73 (123.026)	132.36 (65.195)
	95% CI of Mean	151.92, 199.84	222.10, 309.36	103.45, 161.27

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set**

Parameter (units): Total 1-OHP (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	Geometric Mean (CV%)	128.13 (51.885)	227.58 (52.288)	94.98 (41.831)
	95% CI of Geometric Mean	114.14, 143.83	191.16, 270.92	79.49, 113.50
	Median	131.96	248.99	96.28
	Q25, Q75	91.02, 165.56	153.72, 320.28	75.83, 124.91
	Min, Max	29.9, 406.2	66.1, 565.4	34.7, 182.3
	Mean (SD)	143.75 (72.230)	253.80 (116.012)	102.07 (38.298)
	95% CI of Mean	126.65, 160.85	212.66, 294.94	85.09, 119.06

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set**

Parameter (units): Total 1-OHP (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	Geometric Mean (CV%)	119.82 (46.168)	214.67 (56.278)	85.03 (54.109)
	95% CI of Geometric Mean	107.97, 132.96	178.23, 258.56	67.91, 106.45
	Median	129.82	239.15	79.61
	Q25, Q75	89.33, 160.29	158.98, 312.30	68.99, 102.48
	Min, Max	36.0, 372.0	83.3, 490.4	26.5, 298.1
	Mean (SD)	131.46 (58.995)	242.85 (115.973)	96.66 (57.266)
	95% CI of Mean	117.49, 145.43	201.72, 283.98	71.26, 122.05

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set**

Parameter (units): Total 1-OHP (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	BLOQ, n(%)	2 (2.8)	0	0
	Geometric Mean (CV%)	110.05 (52.045)	221.52 (48.214)	79.71 (74.070)
	95% CI of Geometric Mean	98.00, 123.58	188.37, 260.51	59.45, 106.88
	Median	121.17	229.60	68.83
	Q25, Q75	83.92, 147.60	162.63, 309.45	53.59, 116.33
	Min, Max	19.3, 328.7	82.9, 601.8	23.2, 482.5
	Mean (SD)	122.30 (54.486)	244.65 (112.786)	102.45 (98.247)
	95% CI of Mean	109.40, 135.20	204.65, 284.65	58.88, 146.01

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set**

Parameter (units): Total 1-OHP (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	36	29	13
	Missing, n (%)	4 (10.0)	5 (14.7)	0
	Geometric Mean (CV%)	268.70 (54.899)	222.34 (56.335)	190.40 (43.322)
	95% CI of Geometric Mean	225.86, 319.67	182.09, 271.49	148.18, 244.63
	Median	276.05	207.76	166.82
	Q25, Q75	202.15, 377.44	170.75, 360.13	134.12, 252.17
	Min, Max	65.8, 947.7	65.9, 493.9	122.9, 420.5
	Mean (SD)	303.14 (158.207)	251.54 (121.159)	207.70 (99.015)
	95% CI of Mean	249.60, 356.67	205.45, 297.63	147.87, 267.54

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set**

Parameter (units): Total 1-OHP (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Day 30	n	39	32	13
	Missing, n (%)	1 (2.5)	2 (5.9)	0
	Geometric Mean (CV%)	177.92 (63.797)	290.08 (62.351)	175.33 (65.740)
	95% CI of Geometric Mean	147.21, 215.03	235.93, 356.66	122.05, 251.86
	Median	164.25	328.47	164.17
	Q25, Q75	112.89, 307.35	177.46, 393.82	109.17, 215.09
	Min, Max	49.4, 772.8	107.8, 1090.8	86.9, 618.3
	Mean (SD)	212.01 (142.359)	339.57 (205.297)	212.51 (161.429)
	95% CI of Mean	165.86, 258.16	265.55, 413.60	114.96, 310.07

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set**

Parameter (units): Total 1-OHP (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	36	30	11
	Missing, n (%)	3 (7.7)	5 (14.3)	1 (8.3)
	Geometric Mean (CV%)	247.20 (56.109)	217.36 (57.020)	163.34 (32.436)
	95% CI of Geometric Mean	207.09, 295.07	178.29, 265.00	132.07, 202.02
	Median	257.90	200.64	153.32
	Q25, Q75	196.53, 373.31	159.32, 360.13	130.70, 176.27
	Min, Max	65.8, 947.7	65.9, 493.9	122.9, 387.0
	Mean (SD)	280.78 (153.316)	246.92 (121.720)	172.65 (73.961)
	95% CI of Mean	228.90, 332.66	201.46, 292.37	122.95, 222.34

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set**

Parameter (units): Total 1-OHP (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Day 60	n	39	33	11
	Missing, n (%)	0	2 (5.7)	1 (8.3)
	Geometric Mean (CV%)	168.68 (72.152)	278.86 (71.815)	157.01 (68.150)
	95% CI of Geometric Mean	136.74, 208.07	221.85, 350.51	103.68, 237.76
	Median	150.97	285.44	168.43
	Q25, Q75	111.60, 229.91	190.42, 459.62	88.88, 318.38
	Min, Max	42.3, 2197.5	49.2, 1022.9	58.0, 344.7
	Mean (SD)	229.27 (335.667)	336.43 (212.043)	185.05 (106.169)
	95% CI of Mean	120.45, 338.08	261.24, 411.62	113.72, 256.38

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set**

Parameter (units): Total 1-OHP (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	44	29	9
	Missing, n (%)	3 (6.4)	3 (9.4)	0
	Geometric Mean (CV%)	261.84 (55.642)	211.30 (55.283)	146.37 (12.913)
	95% CI of Geometric Mean	223.59, 306.63	173.61, 257.17	132.59, 161.59
	Median	268.67	193.52	151.91
	Q25, Q75	199.29, 377.44	159.32, 359.98	130.70, 162.00
	Min, Max	65.8, 947.7	65.9, 439.5	122.9, 176.3
	Mean (SD)	297.02 (158.087)	238.40 (114.418)	147.45 (18.943)
	95% CI of Mean	248.95, 345.09	194.87, 281.93	132.89, 162.02

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.1 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - PP Set**

Parameter (units): Total 1-OHP (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Day 90	n	47	32	9
	Geometric Mean (CV%)	197.61 (66.242)	271.96 (55.725)	120.15 (26.638)
	95% CI of Geometric Mean	165.53, 235.90	225.46, 328.05	98.24, 146.94
	Median	200.08	279.95	111.22
	Q25, Q75	125.58, 293.43	196.14, 402.93	110.13, 143.82
	Min, Max	52.6, 739.9	99.7, 763.3	74.7, 190.1
	Mean (SD)	235.48 (147.622)	309.05 (161.817)	123.87 (32.928)
	95% CI of Mean	192.13, 278.83	250.70, 367.39	98.56, 149.19

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	69		36		37	
	Missing, n (%)	11 (13.8)		5 (12.2)		2 (5.1)	
	Geometric Mean (CV%)	145.99 (63.433)		133.67 (68.160)		117.20 (59.640)	
	95% CI of Geometric Mean	126.95, 167.88		108.46, 164.75		97.50, 140.87	
	Median	146.85		138.92		122.39	
	Q25, Q75	106.37, 207.97		84.99, 214.92		81.00, 167.14	
	Min, Max	27.7, 841.5		29.8, 386.7		32.3, 316.9	
	Mean (SD)	172.46 (115.155)		158.78 (91.169)		134.93 (71.661)	
	95% CI of Mean	144.79, 200.13		127.93, 189.63		111.03, 158.83	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	75	69	39	36	37	37
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	2 (5.1)
	Geometric Mean (CV%)	98.34 (57.890)		137.40 (72.304)		85.36 (68.876)	
	95% CI of Geometric Mean	86.89, 111.29		111.35, 169.55		69.34, 105.08	
	Median	95.22	-35.70	132.63	-7.21	91.85	-30.49
	Q25, Q75	63.35, 156.95	-43.05, -21.43	72.23, 244.82	-15.92, 8.98	57.53, 114.52	-38.70, -4.76
	Min, Max	21.3, 312.9	-75.1, 106.0	45.9, 559.3	-45.2, 178.1	18.0, 316.9	-62.6, 83.6
	Mean (SD)	113.06 (61.115)	-29.26 (27.825)	168.73 (113.731)	1.63 (37.924)	102.05 (63.268)	-23.83 (25.389)
	95% CI of Mean	99.00, 127.13	-35.95, -22.57	131.86, 205.60	-11.21, 14.47	80.95, 123.15	-32.30, -15.36

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	75	69	39	36	37	37
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	2 (5.1)
	Geometric Mean (CV%)	93.39 (63.177)		145.05 (64.634)		84.65 (66.673)	
	95% CI of Geometric Mean	81.73, 106.72		119.76, 175.67		69.15, 103.63	
	Median	93.50	-33.68	165.03	-0.35	79.22	-29.53
	Q25, Q75	62.68, 137.21	-49.74, -12.00	84.66, 233.49	-7.53, 24.91	54.92, 119.92	-44.46, 0.00
	Min, Max	16.8, 318.0	-84.5, 58.4	42.1, 400.5	-39.6, 89.4	32.6, 316.9	-71.9, 74.0
	Mean (SD)	109.53 (64.156)	-29.87 (28.704)	169.74 (91.501)	9.47 (32.485)	102.11 (68.882)	-19.57 (38.543)
	95% CI of Mean	94.77, 124.30	-36.77, -22.97	140.07, 199.41	-1.53, 20.46	79.14, 125.08	-32.42, -6.71

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	75	69	39	36	37	37
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	2 (5.1)
	Geometric Mean (CV%)	78.23 (54.610)		135.91 (57.410)		68.23 (71.483)	
	95% CI of Geometric Mean	69.55, 87.99		114.31, 161.59		55.07, 84.54	
	Median	76.95	-44.23	139.38	-1.31	72.86	-40.47
	Q25, Q75	56.32, 117.83	-55.59, -31.26	90.85, 198.58	-18.17, 11.60	50.60, 110.86	-52.37, -28.36
	Min, Max	15.4, 297.8	-83.5, 15.4	48.6, 365.0	-45.6, 63.2	20.4, 316.9	-75.5, 0.0
	Mean (SD)	88.81 (47.636)	-43.09 (18.178)	155.42 (80.690)	0.10 (22.217)	83.84 (60.736)	-38.18 (21.070)
	95% CI of Mean	77.85, 99.78	-47.46, -38.72	129.26, 181.58	-7.42, 7.62	63.59, 104.10	-45.21, -31.15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	75	69	39	36	37	37
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	2 (5.1)
	Geometric Mean (CV%)	72.74 (53.835)		130.78 (58.018)		63.01 (76.218)	
	95% CI of Geometric Mean	64.76, 81.69		109.82, 155.73		50.28, 78.96	
	Median	71.22	-48.41	124.77	-4.71	56.36	-46.58
	Q25, Q75	50.92, 106.29	-60.45, -34.19	75.25, 205.45	-16.71, 8.61	43.36, 88.71	-59.76, -30.99
	Min, Max	17.7, 272.0	-86.8, -5.3	47.0, 327.9	-44.4, 63.2	18.1, 316.9	-79.5, 0.0
	Mean (SD)	82.30 (43.463)	-46.97 (17.443)	149.47 (75.143)	-2.69 (23.032)	79.45 (62.058)	-41.99 (23.189)
	95% CI of Mean	72.30, 92.31	-51.16, -42.77	125.11, 173.84	-10.48, 5.11	58.76, 100.15	-49.72, -34.25

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	75	69	39	36	37	37
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	2 (5.1)
	BLOQ, n(%)	2 (2.7)		0		1 (2.7)	
	Geometric Mean (CV%)	64.98 (54.031)		129.56 (59.239)		53.98 (97.647)	
	95% CI of Geometric Mean	57.84, 73.01		108.45, 154.77		41.09, 70.92	
	Median	71.91	-52.70	130.18	-5.55	52.01	-54.08
	Q25, Q75	46.39, 96.30	-63.80, -44.92	78.33, 194.65	-17.47, 5.63	32.15, 85.81	-68.75, -39.84
	Min, Max	10.0, 220.1	-89.0, 13.6	47.9, 327.8	-50.2, 60.8	7.2, 316.9	-77.8, 0.0
	Mean (SD)	73.03 (35.453)	-53.11 (16.858)	149.18 (78.383)	-4.40 (21.943)	74.18 (65.674)	-49.17 (23.961)
	95% CI of Mean	64.87, 81.19	-57.17, -49.06	123.76, 174.59	-11.83, 3.03	52.28, 96.08	-57.16, -41.17

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	75	69	39	36	37	37
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	2 (5.1)
	Geometric Mean (CV%)	109.54 (66.494)		166.14 (69.560)		104.18 (72.012)	
	95% CI of Geometric Mean	95.30, 125.91		135.53, 203.67		83.98, 129.24	
	Median	107.64	-25.40	183.02	12.95	108.87	-4.84
	Q25, Q75	71.26, 152.98	-46.42, -0.23	119.29, 254.21	-4.86, 30.51	66.98, 147.83	-33.94, 2.20
	Min, Max	27.6, 547.7	-91.5, 216.8	51.7, 739.8	-40.0, 391.5	23.0, 396.6	-62.5, 219.8
	Mean (SD)	132.29 (92.768)	-15.59 (47.160)	200.32 (132.432)	32.26 (76.471)	127.29 (87.905)	0.12 (57.628)
	95% CI of Mean	110.94, 153.64	-26.93, -4.26	157.39, 243.25	6.38, 58.14	97.97, 156.60	-19.10, 19.34

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	75	69	39	36	37	37
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	2 (5.1)
	Geometric Mean (CV%)	114.05 (103.740)		165.23 (68.895)		103.33 (62.154)	
	95% CI of Geometric Mean	93.69, 138.84		135.00, 202.23		85.40, 125.02	
	Median	105.62	-20.27	154.48	13.84	107.91	-19.73
	Q25, Q75	67.29, 161.20	-49.47, 4.25	105.74, 260.65	-7.22, 45.04	80.42, 162.50	-35.44, 5.68
	Min, Max	28.9, 14541.3	-90.8, 7795.6	43.2, 493.2	-66.0, 649.2	25.0, 316.9	-61.3, 256.0
	Mean (SD)	325.11 (1667.492)	97.67 (941.721)	198.51 (122.284)	38.47 (115.049)	119.21 (62.218)	0.52 (61.277)
	95% CI of Mean	-58.55, 708.77	-128.56, 323.91	158.86, 238.15	-0.46, 77.41	98.46, 139.96	-19.91, 20.96

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	75	69	39	36	37	37
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	2 (5.1)
	Geometric Mean (CV%)	116.17 (77.319)		168.96 (62.328)		93.07 (67.063)	
	95% CI of Geometric Mean	99.24, 135.99		140.32, 203.45		75.95, 114.04	
	Median	112.84	-16.48	167.65	22.79	102.05	-19.49
	Q25, Q75	74.79, 177.91	-46.00, 16.60	116.07, 273.61	1.21, 42.04	55.70, 141.18	-34.83, 0.00
	Min, Max	29.1, 697.0	-89.4, 461.8	50.7, 448.3	-32.6, 116.7	17.8, 316.9	-58.9, 36.7
	Mean (SD)	146.51 (111.575)	-2.29 (74.381)	195.98 (103.908)	27.30 (39.531)	109.97 (63.429)	-16.64 (25.162)
	95% CI of Mean	120.83, 172.18	-20.16, 15.58	162.30, 229.67	13.92, 40.68	88.82, 131.12	-25.04, -8.25

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	70	36	37
	Missing, n (%)	10 (12.5)	5 (12.2)	2 (5.1)
	Geometric Mean (CV%)	240.80 (55.676)	213.64 (55.140)	192.90 (52.653)
	95% CI of Geometric Mean	212.74, 272.57	179.46, 254.34	163.57, 227.50
	Median	251.67	201.03	176.20
	Q25, Q75	195.37, 357.86	156.52, 360.05	134.12, 280.24
	Min, Max	51.9, 947.7	65.9, 493.9	74.5, 530.7
	Mean (SD)	272.89 (142.200)	241.45 (117.758)	218.21 (117.375)
	95% CI of Mean	238.98, 306.80	201.60, 281.29	179.07, 257.35

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 1	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	Geometric Mean (CV%)	160.71 (51.272)	221.12 (58.514)	142.06 (58.252)
	95% CI of Geometric Mean	143.80, 179.61	185.45, 263.65	118.62, 170.11
	Median	157.29	223.78	149.80
	Q25, Q75	115.31, 221.71	150.80, 360.80	100.68, 197.19
	Min, Max	43.1, 501.6	90.2, 663.0	50.9, 530.7
	Mean (SD)	180.63 (94.200)	254.86 (140.196)	164.53 (98.428)
	95% CI of Mean	158.95, 202.31	209.41, 300.31	131.71, 197.35

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 2	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	Geometric Mean (CV%)	152.86 (58.409)	236.76 (54.311)	140.00 (65.720)
	95% CI of Geometric Mean	134.94, 173.16	200.78, 279.19	114.65, 170.97
	Median	156.53	233.36	136.84
	Q25, Q75	113.29, 216.58	164.20, 326.42	85.54, 217.12
	Min, Max	34.3, 495.3	85.6, 614.0	53.7, 560.6
	Mean (SD)	176.26 (99.635)	266.84 (130.417)	169.00 (118.985)
	95% CI of Mean	153.34, 199.19	224.56, 309.12	129.32, 208.68

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 3	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	Geometric Mean (CV%)	127.80 (51.460)	218.73 (50.352)	108.55 (64.909)
	95% CI of Geometric Mean	114.31, 142.89	187.49, 255.18	89.08, 132.29
	Median	131.96	228.42	98.16
	Q25, Q75	88.98, 175.38	146.97, 307.33	75.83, 153.85
	Min, Max	29.9, 406.2	66.1, 565.4	34.7, 530.7
	Mean (SD)	143.17 (71.322)	242.88 (111.085)	131.41 (98.365)
	95% CI of Mean	126.75, 159.58	206.87, 278.90	98.61, 164.21

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 4	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	Geometric Mean (CV%)	119.44 (46.295)	209.92 (53.728)	100.96 (73.612)
	95% CI of Geometric Mean	107.92, 132.19	178.30, 247.15	81.07, 125.74
	Median	129.82	206.31	91.12
	Q25, Q75	88.20, 163.17	158.98, 312.30	67.03, 121.81
	Min, Max	36.0, 372.0	83.3, 490.4	26.5, 530.7
	Mean (SD)	131.11 (58.760)	235.74 (110.819)	127.61 (104.567)
	95% CI of Mean	117.59, 144.64	199.81, 271.67	92.74, 162.48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 5	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	BLOQ, n(%)	2 (2.7)	0	1 (2.7)
	Geometric Mean (CV%)	110.11 (51.131)	213.63 (47.893)	91.55 (92.520)
	95% CI of Geometric Mean	98.55, 123.03	184.36, 247.54	70.43, 119.01
	Median	121.17	213.25	82.48
	Q25, Q75	83.92, 147.60	159.64, 309.45	53.59, 136.70
	Min, Max	19.3, 328.7	82.9, 601.8	18.7, 530.7
	Mean (SD)	122.01 (53.639)	235.95 (109.315)	126.60 (119.801)
	95% CI of Mean	109.66, 134.35	200.51, 271.39	86.65, 166.55

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	Geometric Mean (CV%)	177.45 (60.346)	263.28 (67.935)	171.45 (58.453)
	95% CI of Geometric Mean	156.09, 201.73	215.62, 321.47	143.09, 205.42
	Median	164.25	304.77	164.17
	Q25, Q75	120.20, 253.62	163.28, 369.93	119.70, 220.06
	Min, Max	49.4, 824.1	54.0, 1090.8	57.7, 618.3
	Mean (SD)	209.14 (139.711)	314.19 (198.083)	199.68 (126.059)
	95% CI of Mean	176.99, 241.29	249.97, 378.40	157.64, 241.71

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	Geometric Mean (CV%)	182.70 (101.190)	269.23 (70.661)	174.97 (59.768)
	95% CI of Geometric Mean	150.60, 221.63	219.04, 330.91	145.52, 210.38
	Median	175.76	277.07	182.60
	Q25, Q75	110.84, 256.13	166.19, 459.62	108.38, 246.82
	Min, Max	42.3, 23426.3	49.2, 1022.9	58.0, 530.7
	Mean (SD)	527.67 (2691.906)	325.30 (208.978)	201.77 (108.592)
	95% CI of Mean	-91.68, 1147.03	257.55, 393.05	165.56, 237.99

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.7.2 Descriptive Statistics of 1-OHP in 24-hour Urine Collection - FAS****Parameter (units): Total 1-OHP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	Geometric Mean (CV%)	193.95 (69.120)	267.14 (55.674)	151.16 (54.773)
	95% CI of Geometric Mean	167.97, 223.94	225.72, 316.15	127.43, 179.32
	Median	194.81	270.34	155.71
	Q25, Q75	128.97, 287.99	190.42, 396.64	110.78, 189.22
	Min, Max	52.6, 780.0	99.7, 763.3	46.2, 530.7
	Mean (SD)	234.51 (153.127)	304.01 (160.019)	171.98 (96.010)
	95% CI of Mean	199.27, 269.74	252.13, 355.89	139.96, 203.99

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		30		21	
	Missing, n (%)	8 (10.7)		5 (14.3)		3 (12.5)	
	Geometric Mean (CV%)	6.87 (116.650)		6.70 (111.509)		5.32 (125.001)	
	95% CI of Geometric Mean	5.48, 8.62		4.78, 9.38		3.42, 8.28	
	Median	8.86		7.12		3.56	
	Q25, Q75	4.23, 13.31		4.57, 11.00		2.70, 9.62	
	Min, Max	0.2, 55.6		0.9, 73.4		1.3, 51.8	
	Mean (SD)	9.75 (8.580)		10.10 (12.992)		9.05 (12.159)	
	95% CI of Mean	7.65, 11.85		5.24, 14.96		3.51, 14.59	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	3 (4.1)		0		4 (18.2)	
	Geometric Mean (CV%)	1.06 (156.180)		4.82 (133.493)		0.49 (190.376)	
	95% CI of Geometric Mean	0.81, 1.38		3.38, 6.87		0.28, 0.85	
	Median	1.03	-83.06	4.52	-13.71	0.37	-89.11
	Q25, Q75	0.61, 2.21	-87.47, -79.33	2.70, 9.87	-44.21, 13.74	0.23, 0.96	-91.96, -85.87
	Min, Max	0.1, 23.7	-95.7, 0.0	0.6, 73.4	-64.3, 39.4	0.0, 9.5	-98.0, -78.5
	Mean (SD)	1.94 (3.095)	-81.25 (13.313)	8.33 (12.693)	-15.48 (33.402)	1.14 (2.106)	-89.23 (5.218)
	95% CI of Mean	1.21, 2.66	-84.50, -78.00	3.90, 12.77	-27.96, -3.00	0.20, 2.08	-91.61, -86.85

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	12 (16.4)		0		20 (90.9)	
	Geometric Mean (CV%)	0.55 (127.185)		5.21 (149.902)		0.13 (113.437)	
	95% CI of Geometric Mean	0.43, 0.70		3.56, 7.61		0.08, 0.19	
	Median	0.58	-91.65	4.48	-14.21	0.12	-97.49
	Q25, Q75	0.26, 1.13	-95.06, -88.03	2.54, 10.12	-47.82, 7.82	0.08, 0.16	-98.67, -95.78
	Min, Max	0.1, 4.0	-98.0, -31.7	1.0, 79.9	-70.2, 940.5	0.0, 4.6	-99.5, -84.2
	Mean (SD)	0.83 (0.769)	-89.09 (10.516)	10.51 (17.889)	19.14 (178.934)	0.32 (0.955)	-96.59 (3.463)
	95% CI of Mean	0.65, 1.02	-91.66, -86.52	4.26, 16.76	-47.68, 85.96	-0.11, 0.75	-98.18, -95.01

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	9 (12.3)		0		21 (95.5)	
	Geometric Mean (CV%)	0.59 (115.667)		5.28 (123.961)		0.11 (68.888)	
	95% CI of Geometric Mean	0.47, 0.74		3.76, 7.40		0.08, 0.15	
	Median	0.62	-91.42	4.23	-5.47	0.09	-97.79
	Q25, Q75	0.39, 1.10	-94.37, -86.38	2.63, 9.94	-39.38, 9.34	0.08, 0.14	-98.61, -96.64
	Min, Max	0.1, 5.8	-98.2, -27.3	0.8, 73.4	-69.6, 60.7	0.0, 0.6	-99.5, -78.8
	Mean (SD)	0.87 (0.866)	-87.94 (11.298)	8.73 (12.601)	-12.43 (31.688)	0.14 (0.114)	-96.55 (4.823)
	95% CI of Mean	0.66, 1.07	-90.70, -85.18	4.33, 13.14	-24.26, -0.59	0.08, 0.19	-98.75, -94.35

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	6 (8.2)		0		21 (95.5)	
	Geometric Mean (CV%)	0.61 (142.150)		4.52 (129.830)		0.13 (115.384)	
	95% CI of Geometric Mean	0.47, 0.78		3.19, 6.39		0.08, 0.20	
	Median	0.59	-91.18	4.68	-21.60	0.12	-97.72
	Q25, Q75	0.37, 1.08	-95.06, -86.23	2.26, 7.50	-41.44, -5.67	0.09, 0.15	-98.68, -95.91
	Min, Max	0.0, 61.9	-97.8, 436.5	0.8, 73.4	-75.0, 56.4	0.0, 3.3	-99.5, -83.3
	Mean (SD)	1.65 (7.193)	-81.08 (64.891)	7.77 (12.461)	-18.40 (32.586)	0.27 (0.672)	-96.06 (4.656)
	95% CI of Mean	-0.03, 3.34	-96.91, -65.24	3.42, 12.12	-30.57, -6.23	-0.03, 0.57	-98.18, -93.94

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	5 (6.8)		0		22 (100.0)	
	Geometric Mean (CV%)	0.90 (125.231)		6.14 (119.150)		0.12 (53.903)	
	95% CI of Geometric Mean	0.71, 1.13		4.42, 8.53		0.09, 0.15	
	Median	0.91	-88.08	5.49	7.41	0.11	-97.81
	Q25, Q75	0.57, 1.69	-92.34, -76.60	3.00, 14.33	-28.04, 21.70	0.09, 0.17	-98.57, -97.16
	Min, Max	0.0, 6.6	-97.5, 28.1	0.8, 73.4	-75.9, 143.2	0.0, 0.4	-99.7, -84.3
	Mean (SD)	1.35 (1.334)	-79.62 (23.419)	9.70 (12.661)	8.94 (49.081)	0.13 (0.072)	-96.64 (3.840)
	95% CI of Mean	1.03, 1.67	-85.34, -73.90	5.27, 14.12	-9.39, 27.27	0.10, 0.17	-98.40, -94.89

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		29		12	
	Missing, n (%)	3 (7.5)		5 (14.7)		1 (7.7)	
	Geometric Mean (CV%)	7.57 (124.823)		5.81 (99.054)		5.23 (84.617)	
	95% CI of Geometric Mean	5.48, 10.47		4.23, 7.96		3.27, 8.35	
	Median	9.65		6.30		4.37	
	Q25, Q75	5.13, 13.80		4.14, 10.57		2.99, 10.66	
	Min, Max	0.2, 55.6		0.9, 19.5		2.0, 18.7	
	Mean (SD)	10.85 (9.803)		7.66 (5.310)		6.74 (5.196)	
	95% CI of Mean	7.58, 14.13		5.63, 9.68		3.43, 10.05	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	37	33	29	13	12
	Missing, n (%)	0	3 (7.5)	1 (2.9)	5 (14.7)	0	1 (7.7)
	BLOQ, n(%)	3 (7.5)		0		8 (61.5)	
	Geometric Mean (CV%)	1.01 (176.368)		5.08 (133.110)		0.19 (92.988)	
	95% CI of Geometric Mean	0.69, 1.49		3.55, 7.27		0.11, 0.32	
	Median	1.16	-88.27	7.02	16.41	0.18	-96.95
	Q25, Q75	0.43, 1.97	-92.08, -78.02	2.04, 11.71	-29.28, 43.42	0.11, 0.33	-98.53, -93.24
	Min, Max	0.1, 72.9	-97.4, 793.6	0.9, 28.8	-80.4, 143.2	0.0, 0.6	-99.0, -82.2
	Mean (SD)	3.13 (11.374)	-61.31 (144.731)	7.64 (6.248)	12.19 (51.414)	0.25 (0.188)	-94.91 (5.229)
	95% CI of Mean	-0.51, 6.78	-109.57, -13.05	5.42, 9.86	-7.37, 31.75	0.13, 0.37	-98.24, -91.58

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	35		30		11	
	Missing, n (%)	4 (10.3)		5 (14.3)		1 (8.3)	
	Geometric Mean (CV%)	7.65 (131.669)		5.89 (97.350)		4.54 (101.312)	
	95% CI of Geometric Mean	5.41, 10.80		4.34, 8.00		2.58, 7.99	
	Median	9.70		6.60		3.56	
	Q25, Q75	5.42, 14.04		4.14, 10.57		2.32, 11.69	
	Min, Max	0.2, 55.6		0.9, 19.5		1.3, 18.7	
	Mean (SD)	11.01 (9.754)		7.71 (5.224)		6.29 (5.519)	
	95% CI of Mean	7.65, 14.36		5.75, 9.66		2.58, 10.00	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	35	34	30	11	11
	Missing, n (%)	0	4 (10.3)	1 (2.9)	5 (14.3)	1 (8.3)	1 (8.3)
	BLOQ, n(%)	4 (10.3)		0		5 (45.5)	
	Geometric Mean (CV%)	0.88 (122.743)		4.73 (195.019)		0.29 (149.141)	
	95% CI of Geometric Mean	0.64, 1.21		3.05, 7.33		0.13, 0.60	
	Median	1.05	-88.61	4.31	-26.36	0.22	-93.57
	Q25, Q75	0.43, 1.67	-92.94, -79.70	1.95, 9.76	-45.14, 22.55	0.14, 0.39	-97.98, -87.21
	Min, Max	0.1, 7.5	-97.3, -26.6	0.7, 708.1	-82.7, 10165.4	0.1, 4.5	-98.8, -61.7
	Mean (SD)	1.32 (1.333)	-84.57 (13.232)	26.37 (120.525)	326.22 (1858.872)	0.64 (1.283)	-88.86 (12.273)
	95% CI of Mean	0.88, 1.76	-89.12, -80.02	-15.69, 68.42	-367.90, 1020.34	-0.22, 1.51	-97.11, -80.61

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	43		29		9	
	Missing, n (%)	4 (8.5)		3 (9.4)		0	
	Geometric Mean (CV%)	7.80 (127.438)		5.66 (94.808)		4.48 (99.213)	
	95% CI of Geometric Mean	5.76, 10.56		4.17, 7.68		2.37, 8.47	
	Median	9.70		6.30		3.56	
	Q25, Q75	5.40, 14.77		4.14, 9.04		2.92, 6.46	
	Min, Max	0.2, 55.6		0.9, 19.5		1.3, 18.7	
	Mean (SD)	11.21 (9.726)		7.33 (4.880)		6.17 (5.665)	
	95% CI of Mean	8.21, 14.21		5.47, 9.19		1.81, 10.53	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	43	32	29	9	9
	Missing, n (%)	0	4 (8.5)	0	3 (9.4)	0	
	BLOQ, n(%)	2 (4.3)		0		4 (44.4)	
	Geometric Mean (CV%)	0.94 (111.813)		4.47 (110.003)		0.26 (160.299)	
	95% CI of Geometric Mean	0.72, 1.23		3.24, 6.17		0.11, 0.63	
	Median	0.90	-88.58	3.65	-11.55	0.18	-95.28
	Q25, Q75	0.53, 1.66	-93.58, -77.37	2.38, 10.19	-52.31, 30.72	0.12, 0.50	-97.30, -90.85
	Min, Max	0.1, 11.1	-96.5, 36.0	0.8, 19.9	-78.9, 135.0	0.1, 3.0	-99.0, 29.7
	Mean (SD)	1.42 (1.727)	-82.37 (21.022)	6.39 (5.265)	-1.49 (60.173)	0.55 (0.939)	-80.54 (41.633)
	95% CI of Mean	0.91, 1.93	-88.85, -75.90	4.49, 8.30	-24.39, 21.40	-0.17, 1.28	-112.54, -48.53

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	69	30	21
	Missing, n (%)	6 (8.0)	5 (14.3)	3 (12.5)
	Geometric Mean (CV%)	10.90 (122.661)	10.62 (89.526)	8.53 (108.064)
	95% CI of Geometric Mean	8.66, 13.73	7.97, 14.15	5.71, 12.74
	Median	12.01	10.82	7.37
	Q25, Q75	6.23, 21.94	7.81, 16.32	5.06, 15.19
	Min, Max	0.6, 73.7	1.8, 59.1	2.0, 77.5
	Mean (SD)	16.09 (14.650)	13.79 (11.103)	13.24 (16.897)
	95% CI of Mean	12.56, 19.61	9.63, 17.94	5.54, 20.93

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n(%)	3 (4.1)	0	4 (18.2)
	Geometric Mean (CV%)	1.72 (137.327)	7.76 (118.647)	0.79 (148.061)
	95% CI of Geometric Mean	1.35, 2.19	5.59, 10.76	0.48, 1.27
	Median	1.72	7.13	0.74
	Q25, Q75	0.94, 3.16	4.94, 12.46	0.39, 1.21
	Min, Max	0.1, 16.9	1.3, 59.1	0.1, 14.4
	Mean (SD)	2.83 (3.359)	11.82 (12.402)	1.61 (3.049)
	95% CI of Mean	2.05, 3.62	7.49, 16.15	0.25, 2.96

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n(%)	12 (16.4)	0	20 (90.9)
	Geometric Mean (CV%)	0.91 (119.719)	8.49 (130.996)	0.20 (111.666)
	95% CI of Geometric Mean	0.73, 1.14	5.98, 12.04	0.13, 0.31
	Median	0.92	7.86	0.18
	Q25, Q75	0.55, 1.74	4.03, 15.03	0.14, 0.25
	Min, Max	0.1, 7.0	1.6, 98.7	0.1, 6.5
	Mean (SD)	1.38 (1.361)	14.43 (19.255)	0.48 (1.359)
	95% CI of Mean	1.06, 1.70	7.70, 21.15	-0.13, 1.09

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n(%)	9 (12.3)	0	21 (95.5)
	Geometric Mean (CV%)	0.98 (117.263)	8.57 (109.766)	0.17 (73.523)
	95% CI of Geometric Mean	0.79, 1.23	6.28, 11.70	0.12, 0.23
	Median	1.04	8.70	0.15
	Q25, Q75	0.61, 1.99	4.71, 19.29	0.10, 0.21
	Min, Max	0.1, 9.9	1.8, 59.1	0.1, 0.8
	Mean (SD)	1.46 (1.476)	12.59 (12.289)	0.22 (0.200)
	95% CI of Mean	1.11, 1.80	8.30, 16.88	0.13, 0.31

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n(%)	6 (8.2)	0	21 (95.5)
	Geometric Mean (CV%)	1.01 (140.070)	7.20 (115.912)	0.20 (114.718)
	95% CI of Geometric Mean	0.79, 1.29	5.21, 9.94	0.13, 0.31
	Median	1.00	8.77	0.16
	Q25, Q75	0.56, 1.63	3.39, 13.50	0.13, 0.26
	Min, Max	0.1, 110.6	1.0, 59.1	0.0, 4.3
	Mean (SD)	2.87 (12.856)	10.69 (11.061)	0.40 (0.893)
	95% CI of Mean	-0.14, 5.87	6.83, 14.56	0.00, 0.80

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n(%)	5 (6.8)	0	22 (100.0)
	Geometric Mean (CV%)	1.54 (122.541)	10.03 (108.690)	0.20 (52.849)
	95% CI of Geometric Mean	1.23, 1.93	7.36, 13.65	0.15, 0.25
	Median	1.48	9.28	0.21
	Q25, Q75	0.97, 2.91	6.17, 19.99	0.14, 0.25
	Min, Max	0.1, 12.7	1.6, 59.1	0.1, 0.9
	Mean (SD)	2.36 (2.543)	14.23 (12.330)	0.23 (0.169)
	95% CI of Mean	1.76, 2.96	9.92, 18.53	0.15, 0.31

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (ng)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	38	29	12
	Missing, n (%)	2 (5.0)	5 (14.7)	1 (7.7)
	Geometric Mean (CV%)	11.76 (131.515)	9.52 (86.033)	8.19 (77.326)
	95% CI of Geometric Mean	8.46, 16.36	7.17, 12.64	5.30, 12.66
	Median	12.13	10.26	7.76
	Q25, Q75	7.09, 25.67	7.01, 15.67	4.43, 16.56
	Min, Max	0.6, 62.6	1.8, 31.4	3.0, 20.0
	Mean (SD)	17.40 (15.240)	11.90 (7.416)	10.06 (6.445)
	95% CI of Mean	12.39, 22.42	9.08, 14.73	5.96, 14.15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set**

Parameter (units): NNN (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Day 30	n	40	33	13
	Missing, n (%)	0	1 (2.9)	0
	BLOQ, n(%)	3 (7.5)	0	8 (61.5)
	Geometric Mean (CV%)	1.64 (163.579)	8.47 (117.142)	0.32 (95.727)
	95% CI of Geometric Mean	1.14, 2.37	6.09, 11.79	0.19, 0.52
	Median	1.39	11.63	0.28
	Q25, Q75	0.71, 3.66	3.86, 16.27	0.22, 0.55
	Min, Max	0.2, 91.5	1.7, 47.4	0.1, 1.3
	Mean (SD)	4.44 (14.240)	12.17 (10.053)	0.43 (0.359)
	95% CI of Mean	-0.12, 9.00	8.60, 15.74	0.21, 0.65

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (ng)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	37	30	11
	Missing, n (%)	2 (5.1)	5 (14.3)	1 (8.3)
	Geometric Mean (CV%)	11.58 (146.392)	9.60 (84.302)	7.35 (98.546)
	95% CI of Geometric Mean	8.10, 16.54	7.29, 12.62	4.22, 12.79
	Median	13.60	10.50	7.06
	Q25, Q75	7.09, 24.01	7.01, 15.67	3.68, 18.37
	Min, Max	0.6, 62.6	1.8, 31.4	2.0, 20.0
	Mean (SD)	17.75 (15.435)	11.91 (7.288)	9.74 (7.048)
	95% CI of Mean	12.60, 22.90	9.18, 14.64	5.00, 14.48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (ng)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Day 60	n	39	34	11
	Missing, n (%)	0	1 (2.9)	1 (8.3)
	BLOQ, n(%)	4 (10.3)	0	5 (45.5)
	Geometric Mean (CV%)	1.43 (119.236)	7.92 (193.303)	0.48 (162.256)
	95% CI of Geometric Mean	1.05, 1.95	5.12, 12.25	0.22, 1.04
	Median	1.65	8.14	0.48
	Q25, Q75	0.77, 2.55	2.92, 14.52	0.17, 0.70
	Min, Max	0.2, 15.3	1.5, 1106.1	0.1, 8.1
	Mean (SD)	2.20 (2.578)	42.02 (188.177)	1.13 (2.323)
	95% CI of Mean	1.36, 3.04	-23.64, 107.69	-0.43, 2.70

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (ng)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	45	29	9
	Missing, n (%)	2 (4.3)	3 (9.4)	0
	Geometric Mean (CV%)	11.82 (141.222)	9.26 (82.296)	7.27 (92.990)
	95% CI of Geometric Mean	8.63, 16.20	7.04, 12.18	3.96, 13.34
	Median	12.60	10.26	7.06
	Q25, Q75	7.35, 24.01	7.01, 15.28	3.74, 14.74
	Min, Max	0.6, 73.7	1.8, 31.4	2.0, 19.5
	Mean (SD)	18.21 (16.730)	11.40 (6.844)	9.35 (6.573)
	95% CI of Mean	13.18, 23.24	8.79, 14.01	4.30, 14.41

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.1 Descriptive Statistics of Total NNN in 24-hour Urine Collection - PP Set****Parameter (units): NNN (ng)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Day 90	n	47	32	9
	BLOQ, n(%)	2 (4.3)	0	4 (44.4)
	Geometric Mean (CV%)	1.58 (98.968)	7.43 (100.526)	0.45 (206.831)
	95% CI of Geometric Mean	1.24, 2.02	5.49, 10.05	0.16, 1.21
	Median	1.44	7.05	0.37
	Q25, Q75	0.93, 2.75	3.31, 15.13	0.17, 0.63
	Min, Max	0.2, 14.0	1.9, 34.8	0.1, 8.2
	Mean (SD)	2.24 (2.325)	10.26 (8.324)	1.27 (2.626)
	95% CI of Mean	1.55, 2.93	7.26, 13.27	-0.76, 3.29

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		36		36	
	Missing, n (%)	9 (11.3)		5 (12.2)		3 (7.7)	
	Geometric Mean (CV%)	7.25 (122.844)		7.01 (111.428)		5.86 (115.623)	
	95% CI of Geometric Mean	5.77, 9.10		5.17, 9.51		4.28, 8.01	
	Median	8.89		8.05		5.61	
	Q25, Q75	4.41, 13.31		4.65, 11.67		3.03, 11.86	
	Min, Max	0.2, 101.6		0.9, 73.4		0.9, 51.8	
	Mean (SD)	11.07 (13.731)		10.37 (12.269)		9.08 (10.304)	
	95% CI of Mean	7.81, 14.32		6.21, 14.52		5.59, 12.57	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	3 (3.9)		0		5 (13.5)	
	Geometric Mean (CV%)	1.11 (157.573)		5.14 (126.175)		0.75 (256.107)	
	95% CI of Geometric Mean	0.85, 1.43		3.75, 7.02		0.46, 1.20	
	Median	1.09	-83.06	5.25	-17.39	0.52	-88.86
	Q25, Q75	0.61, 2.31	-87.49, -79.74	2.70, 9.41	-41.48, 11.03	0.29, 2.06	-92.63, -83.09
	Min, Max	0.1, 23.7	-95.7, 0.0	0.6, 73.4	-64.3, 39.4	0.0, 13.7	-98.0, 0.0
	Mean (SD)	2.04 (3.180)	-81.47 (13.015)	8.39 (11.815)	-15.29 (31.683)	1.91 (2.910)	-76.85 (31.676)
	95% CI of Mean	1.31, 2.76	-84.55, -78.38	4.61, 12.17	-26.01, -4.56	0.94, 2.89	-87.57, -66.13

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	12 (15.6)		0		30 (81.1)	
	Geometric Mean (CV%)	0.57 (124.597)		5.52 (145.394)		0.19 (321.981)	
	95% CI of Geometric Mean	0.45, 0.72		3.92, 7.77		0.11, 0.33	
	Median	0.63	-91.65	5.92	-11.87	0.12	-97.66
	Q25, Q75	0.29, 1.14	-95.06, -88.03	2.63, 10.15	-44.72, 0.02	0.08, 0.18	-98.98, -94.76
	Min, Max	0.1, 4.0	-98.9, -31.7	1.0, 79.9	-70.2, 940.5	0.0, 13.7	-99.7, 0.0
	Mean (SD)	0.85 (0.754)	-89.19 (10.337)	10.52 (16.745)	13.91 (163.353)	1.09 (2.665)	-83.50 (34.147)
	95% CI of Mean	0.67, 1.02	-91.64, -86.74	5.16, 15.88	-41.37, 69.18	0.19, 1.98	-95.06, -71.95

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	9 (11.7)		0		31 (83.8)	
	Geometric Mean (CV%)	0.62 (116.696)		5.76 (118.220)		0.19 (278.180)	
	95% CI of Geometric Mean	0.50, 0.77		4.27, 7.78		0.11, 0.31	
	Median	0.63	-91.42	6.25	-6.85	0.10	-97.72
	Q25, Q75	0.41, 1.12	-94.37, -87.00	3.02, 10.72	-35.19, 7.43	0.09, 0.21	-98.78, -95.48
	Min, Max	0.1, 5.8	-98.2, -27.3	0.8, 73.4	-69.6, 193.5	0.0, 13.7	-99.7, 0.0
	Mean (SD)	0.91 (0.920)	-88.19 (11.032)	9.08 (11.921)	-6.60 (44.876)	0.98 (2.598)	-83.37 (34.194)
	95% CI of Mean	0.70, 1.12	-90.80, -85.57	5.26, 12.89	-21.79, 8.59	0.11, 1.85	-94.95, -71.80

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	6 (7.8)		0		31 (83.8)	
	Geometric Mean (CV%)	0.62 (137.897)		5.00 (124.770)		0.20 (306.975)	
	95% CI of Geometric Mean	0.48, 0.79		3.66, 6.82		0.12, 0.34	
	Median	0.61	-91.18	5.53	-17.91	0.12	-97.83
	Q25, Q75	0.39, 1.08	-95.06, -85.62	2.74, 8.08	-40.54, -5.58	0.09, 0.22	-98.75, -92.66
	Min, Max	0.0, 61.9	-99.5, 436.5	0.8, 73.4	-75.0, 238.2	0.0, 13.7	-99.7, 0.0
	Mean (SD)	1.62 (7.003)	-81.63 (63.070)	8.16 (11.782)	-11.40 (52.475)	1.06 (2.622)	-83.06 (34.078)
	95% CI of Mean	0.02, 3.21	-96.57, -66.70	4.39, 11.93	-29.16, 6.36	0.18, 1.94	-94.59, -71.52

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	5 (6.5)		0		32 (86.5)	
	Geometric Mean (CV%)	0.91 (121.785)		6.62 (114.782)		0.21 (245.224)	
	95% CI of Geometric Mean	0.73, 1.13		4.93, 8.88		0.13, 0.34	
	Median	0.91	-88.36	6.46	5.69	0.15	-97.61
	Q25, Q75	0.59, 1.69	-92.52, -76.60	3.92, 14.18	-23.10, 20.50	0.10, 0.18	-98.60, -94.64
	Min, Max	0.0, 6.6	-99.4, 28.1	0.8, 73.4	-75.9, 147.6	0.0, 13.7	-99.7, 0.0
	Mean (SD)	1.34 (1.307)	-80.03 (23.008)	10.10 (12.161)	11.40 (50.709)	0.99 (2.594)	-83.19 (34.089)
	95% CI of Mean	1.04, 1.65	-85.49, -74.58	6.21, 13.99	-5.76, 28.56	0.12, 1.86	-94.73, -71.65

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	5 (6.5)		0		17 (45.9)	
	Geometric Mean (CV%)	1.07 (186.091)		6.09 (146.346)		0.41 (291.871)	
	95% CI of Geometric Mean	0.81, 1.42		4.32, 8.58		0.24, 0.68	
	Median	0.96	-86.28	8.13	10.73	0.29	-93.62
	Q25, Q75	0.57, 1.93	-91.80, -77.04	2.42, 12.47	-24.71, 40.91	0.12, 1.04	-97.64, -84.89
	Min, Max	0.1, 72.9	-97.4, 793.6	0.9, 73.4	-80.4, 143.2	0.0, 13.7	-99.7, 0.0
	Mean (SD)	3.43 (11.414)	-61.67 (125.258)	10.11 (12.222)	10.04 (48.554)	1.39 (2.683)	-79.21 (33.327)
	95% CI of Mean	0.84, 6.03	-91.32, -32.02	6.20, 14.02	-6.39, 26.47	0.49, 2.29	-90.49, -67.93

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	5 (6.5)		0		10 (27.0)	
	Geometric Mean (CV%)	0.96 (118.122)		5.68 (207.472)		0.58 (286.447)	
	95% CI of Geometric Mean	0.78, 1.20		3.75, 8.59		0.35, 0.96	
	Median	1.02	-86.35	5.08	-18.96	0.52	-90.89
	Q25, Q75	0.55, 1.67	-92.22, -76.14	2.44, 10.42	-43.07, 20.35	0.15, 1.93	-95.02, -71.97
	Min, Max	0.1, 7.5	-99.0, -13.2	0.7, 708.1	-82.7, 10165.4	0.1, 13.7	-99.4, 0.0
	Mean (SD)	1.45 (1.489)	-81.95 (15.196)	26.10 (111.237)	272.81 (1696.471)	1.64 (2.654)	-75.69 (33.477)
	95% CI of Mean	1.11, 1.79	-85.55, -78.35	-9.48, 61.68	-301.20, 846.81	0.75, 2.53	-87.02, -64.35

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	3 (3.9)		0		7 (18.9)	
	Geometric Mean (CV%)	0.99 (121.636)		5.33 (130.939)		0.79 (396.430)	
	95% CI of Geometric Mean	0.79, 1.24		3.87, 7.35		0.45, 1.40	
	Median	0.92	-85.91	5.20	-10.26	0.66	-86.24
	Q25, Q75	0.60, 1.81	-92.11, -73.87	2.49, 11.11	-47.10, 19.34	0.20, 3.01	-95.07, -50.58
	Min, Max	0.1, 11.1	-98.4, 36.0	0.8, 73.4	-78.9, 135.0	0.1, 142.3	-99.0, 174.5
	Mean (SD)	1.55 (1.825)	-80.15 (20.649)	8.87 (12.025)	-3.54 (54.956)	5.58 (23.251)	-63.23 (55.131)
	95% CI of Mean	1.13, 1.97	-85.04, -75.26	5.02, 12.72	-22.14, 15.06	-2.18, 13.33	-81.89, -44.57

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	73	36	36
	Missing, n (%)	7 (8.8)	5 (12.2)	3 (7.7)
	Geometric Mean (CV%)	11.53 (128.047)	11.21 (91.714)	9.59 (108.204)
	95% CI of Geometric Mean	9.16, 14.51	8.60, 14.60	7.11, 12.92
	Median	12.60	11.68	8.08
	Q25, Q75	6.36, 21.94	8.11, 18.88	5.11, 18.00
	Min, Max	0.6, 152.4	1.8, 59.1	2.0, 77.5
	Mean (SD)	18.02 (21.381)	14.55 (10.973)	14.41 (15.526)
	95% CI of Mean	13.03, 23.01	10.83, 18.27	9.15, 19.67

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 1	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n(%)	3 (3.9)	0	5 (13.5)
	Geometric Mean (CV%)	1.79 (138.804)	8.26 (111.182)	1.24 (221.088)
	95% CI of Geometric Mean	1.41, 2.28	6.19, 11.01	0.79, 1.94
	Median	1.77	7.69	0.98
	Q25, Q75	0.97, 3.16	5.00, 15.52	0.50, 4.17
	Min, Max	0.1, 16.9	1.3, 59.1	0.1, 30.6
	Mean (SD)	2.99 (3.587)	12.01 (11.578)	3.18 (5.665)
	95% CI of Mean	2.17, 3.81	8.30, 15.71	1.28, 5.07

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 2	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n(%)	12 (15.6)	0	30 (81.1)
	Geometric Mean (CV%)	0.94 (117.274)	8.99 (126.113)	0.32 (319.815)
	95% CI of Geometric Mean	0.76, 1.17	6.58, 12.29	0.19, 0.54
	Median	0.98	8.88	0.19
	Q25, Q75	0.55, 1.74	4.51, 17.28	0.14, 0.30
	Min, Max	0.1, 7.0	1.6, 98.7	0.1, 30.6
	Mean (SD)	1.40 (1.333)	14.59 (18.015)	1.95 (5.469)
	95% CI of Mean	1.09, 1.71	8.82, 20.35	0.12, 3.78

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 3	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n(%)	9 (11.7)	0	31 (83.8)
	Geometric Mean (CV%)	1.02 (117.393)	9.31 (104.298)	0.30 (291.579)
	95% CI of Geometric Mean	0.82, 1.27	7.07, 12.26	0.18, 0.50
	Median	1.07	9.58	0.18
	Q25, Q75	0.61, 1.99	4.85, 20.01	0.12, 0.31
	Min, Max	0.1, 9.9	1.8, 59.1	0.1, 30.6
	Mean (SD)	1.51 (1.523)	13.14 (11.683)	1.80 (5.415)
	95% CI of Mean	1.16, 1.86	9.39, 16.88	-0.01, 3.61

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 4	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n(%)	6 (7.8)	0	31 (83.8)
	Geometric Mean (CV%)	1.02 (135.735)	8.01 (111.995)	0.32 (317.821)
	95% CI of Geometric Mean	0.81, 1.30	6.00, 10.70	0.19, 0.55
	Median	1.02	9.17	0.19
	Q25, Q75	0.60, 1.85	4.20, 13.83	0.13, 0.29
	Min, Max	0.1, 110.6	1.0, 59.1	0.0, 30.6
	Mean (SD)	2.80 (12.518)	11.49 (10.686)	1.90 (5.425)
	95% CI of Mean	-0.05, 5.64	8.07, 14.91	0.09, 3.72

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 5	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n(%)	5 (6.5)	0	32 (86.5)
	Geometric Mean (CV%)	1.55 (120.260)	10.87 (104.508)	0.36 (247.566)
	95% CI of Geometric Mean	1.25, 1.93	8.26, 14.32	0.22, 0.58
	Median	1.48	10.88	0.21
	Q25, Q75	0.97, 2.91	6.48, 21.47	0.18, 0.37
	Min, Max	0.1, 12.7	1.6, 59.1	0.1, 30.6
	Mean (SD)	2.36 (2.509)	15.00 (12.004)	1.83 (5.407)
	95% CI of Mean	1.78, 2.93	11.16, 18.85	0.02, 3.64

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n(%)	5 (6.5)	0	17 (45.9)
	Geometric Mean (CV%)	1.75 (176.936)	9.65 (125.825)	0.68 (277.423)
	95% CI of Geometric Mean	1.33, 2.30	7.06, 13.18	0.41, 1.11
	Median	1.41	12.25	0.51
	Q25, Q75	0.82, 3.57	4.55, 18.92	0.22, 1.71
	Min, Max	0.1, 148.7	1.7, 59.1	0.1, 30.6
	Mean (SD)	5.60 (19.706)	14.33 (12.450)	2.36 (5.383)
	95% CI of Mean	1.13, 10.08	10.35, 18.32	0.56, 4.16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n(%)	5 (6.5)	0	10 (27.0)
	Geometric Mean (CV%)	1.56 (112.167)	9.25 (193.958)	0.99 (260.675)
	95% CI of Geometric Mean	1.26, 1.92	6.20, 13.80	0.61, 1.60
	Median	1.65	10.68	0.70
	Q25, Q75	0.89, 2.83	3.54, 18.47	0.43, 2.57
	Min, Max	0.2, 15.3	1.5, 1106.1	0.1, 30.6
	Mean (SD)	2.32 (2.481)	40.04 (173.291)	2.79 (5.382)
	95% CI of Mean	1.75, 2.89	-15.38, 95.47	0.99, 4.59

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.8.2 Descriptive Statistics of Total NNN in 24-hour Urine Collection - FAS****Parameter (units): NNN (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n(%)	3 (3.9)	0	7 (18.9)
	Geometric Mean (CV%)	1.67 (108.018)	8.44 (111.540)	1.30 (359.806)
	95% CI of Geometric Mean	1.36, 2.04	6.32, 11.25	0.75, 2.23
	Median	1.56	8.49	1.01
	Q25, Q75	0.95, 2.90	3.82, 17.21	0.37, 3.67
	Min, Max	0.2, 14.0	1.9, 59.1	0.1, 155.1
	Mean (SD)	2.45 (2.592)	12.32 (11.455)	7.17 (25.568)
	95% CI of Mean	1.86, 3.04	8.65, 15.99	-1.36, 15.70

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set****Parameter (units): 4-ABP (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		30		21	
	Missing, n (%)	8 (10.7)		5 (14.3)		3 (12.5)	
	BLOQ, n(%)	2 (3.0)		0		0	
	Geometric Mean (CV%)	10.76 (83.399)		11.59 (60.025)		9.78 (77.787)	
	95% CI of Geometric Mean	9.01, 12.86		9.42, 14.26		7.14, 13.38	
	Median	12.16		11.27		8.60	
	Q25, Q75	7.89, 15.71		8.06, 14.26		6.78, 13.57	
	Min, Max	0.4, 58.8		4.3, 47.8		2.6, 42.4	
	Mean (SD)	13.15 (8.527)		13.63 (9.186)		12.43 (10.002)	
	95% CI of Mean	11.06, 15.23		10.20, 17.06		7.87, 16.99	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set****Parameter (units): 4-ABP (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	5 (6.8)		0		0	
	Geometric Mean (CV%)	5.47 (81.128)		10.94 (70.475)		5.59 (65.975)	
	95% CI of Geometric Mean	4.63, 6.46		8.76, 13.66		4.28, 7.30	
	Median	5.67	-51.48	10.93	-0.50	4.72	-44.84
	Q25, Q75	3.92, 8.09	-58.05, -35.38	7.05, 16.58	-22.05, 19.50	3.70, 6.78	-54.14, -30.98
	Min, Max	0.4, 41.3	-81.0, 39.6	3.4, 47.8	-53.4, 107.5	3.0, 25.4	-69.6, 67.0
	Mean (SD)	6.90 (5.811)	-43.36 (25.657)	13.43 (9.773)	4.34 (34.294)	6.98 (6.227)	-37.71 (32.552)
	95% CI of Mean	5.54, 8.26	-49.62, -37.09	10.01, 16.84	-8.47, 17.15	4.21, 9.74	-52.54, -22.89

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set****Parameter (units): 4-ABP (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	21 (28.8)		0		6 (27.3)	
	Geometric Mean (CV%)	2.52 (90.034)		9.44 (79.653)		2.46 (88.693)	
	95% CI of Geometric Mean	2.10, 3.03		7.39, 12.06		1.75, 3.45	
	Median	2.44	-75.05	9.11	-15.83	2.65	-71.73
	Q25, Q75	1.58, 4.40	-83.59, -64.99	5.94, 15.57	-40.39, 5.61	1.56, 3.81	-81.04, -63.30
	Min, Max	0.5, 18.4	-92.5, 43.6	2.4, 47.8	-70.2, 196.6	0.7, 12.0	-91.7, -38.3
	Mean (SD)	3.41 (3.079)	-70.87 (21.085)	11.96 (9.158)	-5.23 (52.503)	3.27 (2.860)	-70.31 (14.342)
	95% CI of Mean	2.68, 4.13	-76.01, -65.72	8.76, 15.16	-24.84, 14.38	2.00, 4.55	-76.85, -63.78

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set****Parameter (units): 4-ABP (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	25 (34.2)		0		8 (36.4)	
	Geometric Mean (CV%)	2.11 (86.345)		11.66 (65.805)		2.32 (110.228)	
	95% CI of Geometric Mean	1.77, 2.52		9.45, 14.38		1.56, 3.45	
	Median	2.05	-80.62	10.79	3.54	2.17	-79.36
	Q25, Q75	1.33, 3.05	-87.69, -73.35	8.53, 17.16	-13.26, 32.06	1.06, 3.72	-86.85, -54.17
	Min, Max	0.6, 25.7	-96.6, 384.2	3.4, 47.8	-56.3, 83.2	0.7, 11.2	-91.7, 23.5
	Mean (SD)	2.96 (3.556)	-70.64 (58.326)	14.05 (9.974)	8.01 (35.106)	3.46 (3.397)	-66.45 (32.479)
	95% CI of Mean	2.12, 3.79	-84.87, -56.41	10.56, 17.53	-5.10, 21.13	1.95, 4.97	-81.24, -51.66

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set****Parameter (units): 4-ABP (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	40 (54.8)		0		14 (63.6)	
	Geometric Mean (CV%)	1.61 (84.095)		10.54 (65.230)		1.47 (98.171)	
	95% CI of Geometric Mean	1.35, 1.91		8.56, 12.98		1.02, 2.13	
	Median	1.42	-85.15	11.46	1.62	1.18	-87.08
	Q25, Q75	1.07, 2.23	-92.49, -75.42	7.55, 14.80	-33.72, 26.58	0.82, 2.88	-89.99, -80.02
	Min, Max	0.3, 19.2	-98.1, 32.2	3.4, 47.8	-57.0, 77.1	0.3, 6.5	-95.3, -36.7
	Mean (SD)	2.23 (2.668)	-78.57 (22.245)	12.52 (8.342)	3.78 (39.532)	2.07 (1.885)	-79.26 (18.065)
	95% CI of Mean	1.60, 2.86	-84.00, -73.14	9.61, 15.44	-10.99, 18.55	1.23, 2.91	-87.48, -71.03

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set****Parameter (units): 4-ABP (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	50 (68.5)		1 (2.9)		14 (63.6)	
	Geometric Mean (CV%)	1.76 (78.013)		9.63 (68.207)		1.44 (78.057)	
	95% CI of Geometric Mean	1.50, 2.08		7.76, 11.95		1.06, 1.97	
	Median	1.56	-86.56	9.47	-9.93	1.29	-87.37
	Q25, Q75	1.12, 2.60	-90.73, -70.67	6.77, 15.14	-30.60, 14.58	0.77, 2.63	-90.60, -70.94
	Min, Max	0.6, 17.3	-95.5, 207.8	1.8, 47.8	-77.3, 79.2	0.5, 5.4	-97.1, -44.1
	Mean (SD)	2.34 (2.448)	-73.78 (41.219)	11.63 (8.384)	-7.13 (37.301)	1.83 (1.354)	-80.83 (14.451)
	95% CI of Mean	1.77, 2.92	-83.84, -63.72	8.70, 14.56	-21.06, 6.80	1.22, 2.43	-87.41, -74.25

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set****Parameter (units): 4-ABP (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		29		12	
	Missing, n (%)	3 (7.5)		5 (14.7)		1 (7.7)	
	BLOQ, n(%)	1 (2.7)		0		0	
	Geometric Mean (CV%)	10.23 (94.579)		10.72 (56.338)		11.24 (69.478)	
	95% CI of Geometric Mean	7.83, 13.36		8.78, 13.10		7.54, 16.75	
	Median	12.02		11.10		10.11	
	Q25, Q75	7.80, 14.92		8.00, 13.26		8.33, 16.29	
	Min, Max	0.4, 58.8		4.2, 32.3		4.7, 42.4	
	Mean (SD)	12.90 (9.455)		12.26 (6.801)		13.73 (10.546)	
	95% CI of Mean	9.74, 16.05		9.67, 14.85		7.03, 20.44	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set****Parameter (units): 4-ABP (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	37	33	29	13	12
	Missing, n (%)	0	3 (7.5)	1 (2.9)	5 (14.7)	0	1 (7.7)
	BLOQ, n(%)	10 (25.0)		1 (3.0)		3 (23.1)	
	Geometric Mean (CV%)	3.36 (109.027)		12.52 (75.306)		3.87 (109.986)	
	95% CI of Geometric Mean	2.52, 4.46		9.87, 15.88		2.26, 6.64	
	Median	3.66	-66.06	10.72	36.65	4.02	-70.54
	Q25, Q75	2.19, 5.77	-82.41, -35.02	8.93, 21.72	-8.83, 65.84	2.39, 6.58	-79.63, -49.86
	Min, Max	0.5, 20.9	-98.6, 57.2	2.0, 44.1	-57.4, 178.8	0.6, 14.8	-94.7, 63.5
	Mean (SD)	4.77 (4.268)	-54.52 (38.481)	15.36 (10.039)	33.37 (57.222)	5.33 (4.250)	-49.39 (54.297)
	95% CI of Mean	3.40, 6.14	-67.36, -41.69	11.79, 18.92	11.60, 55.14	2.75, 7.90	-83.90, -14.89

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set****Parameter (units): 4-ABP (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	35		30		11	
	Missing, n (%)	4 (10.3)		5 (14.3)		1 (8.3)	
	BLOQ, n(%)	1 (2.9)		0		0	
	Geometric Mean (CV%)	11.44 (100.469)		10.69 (55.256)		8.81 (70.650)	
	95% CI of Geometric Mean	8.58, 15.25		8.81, 12.97		5.74, 13.52	
	Median	13.13		11.02		9.05	
	Q25, Q75	9.65, 16.62		8.00, 13.26		4.90, 12.51	
	Min, Max	0.4, 58.8		4.2, 32.3		2.6, 23.1	
	Mean (SD)	14.55 (10.316)		12.18 (6.698)		10.45 (6.279)	
	95% CI of Mean	11.00, 18.10		9.67, 14.68		6.23, 14.68	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set****Parameter (units): 4-ABP (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	35	34	30	11	11
	Missing, n (%)	0	4 (10.3)	1 (2.9)	5 (14.3)	1 (8.3)	1 (8.3)
	BLOQ, n(%)	6 (15.4)		1 (2.9)		2 (18.2)	
	Geometric Mean (CV%)	3.77 (85.360)		11.33 (92.156)		3.97 (110.175)	
	95% CI of Geometric Mean	2.96, 4.80		8.62, 14.91		2.17, 7.22	
	Median	3.19	-69.68	13.59	23.92	4.79	-55.61
	Q25, Q75	2.70, 6.26	-79.08, -50.77	5.87, 21.66	-17.98, 47.45	1.67, 7.70	-71.78, -35.67
	Min, Max	0.5, 17.3	-92.9, 124.3	1.4, 37.0	-82.5, 181.8	1.1, 16.0	-87.5, 156.2
	Mean (SD)	4.92 (4.009)	-57.93 (41.346)	14.65 (9.784)	25.17 (60.053)	5.55 (4.716)	-38.54 (66.791)
	95% CI of Mean	3.61, 6.22	-72.14, -43.72	11.23, 18.07	2.74, 47.60	2.38, 8.72	-83.41, 6.34

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set****Parameter (units): 4-ABP (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	43		29		9	
	Missing, n (%)	4 (8.5)		3 (9.4)		0	
	BLOQ, n(%)	1 (2.3)		0		0	
	Geometric Mean (CV%)	11.46 (92.111)		10.61 (56.174)		7.71 (66.131)	
	95% CI of Geometric Mean	9.00, 14.59		8.69, 12.95		4.85, 12.25	
	Median	13.13		10.95		8.60	
	Q25, Q75	8.61, 16.73		8.00, 13.08		4.90, 10.21	
	Min, Max	0.4, 58.8		4.2, 32.3		2.6, 20.1	
	Mean (SD)	14.28 (9.695)		12.14 (6.814)		8.97 (5.171)	
	95% CI of Mean	11.29, 17.27		9.54, 14.74		4.99, 12.95	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set****Parameter (units): 4-ABP (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	43	32	29	9	9
	Missing, n (%)	0	4 (8.5)	0	3 (9.4)	0	
	BLOQ, n(%)	11 (23.4)		1 (3.1)		4 (44.4)	
	Geometric Mean (CV%)	3.77 (113.522)		11.31 (80.953)		2.98 (128.329)	
	95% CI of Geometric Mean	2.88, 4.93		8.75, 14.61		1.39, 6.37	
	Median	4.24	-72.22	11.63	14.84	1.96	-65.25
	Q25, Q75	2.17, 6.67	-80.21, -36.93	8.01, 21.27	1.44, 43.78	1.66, 6.88	-81.13, -14.67
	Min, Max	0.6, 30.6	-98.6, 138.3	1.7, 35.5	-78.5, 127.6	0.9, 11.0	-90.2, 134.8
	Mean (SD)	5.55 (5.562)	-54.19 (45.675)	13.95 (8.611)	22.21 (48.190)	4.48 (4.018)	-35.58 (72.801)
	95% CI of Mean	3.91, 7.19	-68.26, -40.13	10.84, 17.06	3.87, 40.54	1.39, 7.57	-91.54, 20.39

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set**

Parameter (units): 4-ABP (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	70	31	22
	Missing, n (%)	5 (6.7)	4 (11.4)	2 (8.3)
	BLOQ, n(%)	2 (2.9)	0	0
	Geometric Mean (CV%)	17.83 (83.923)	18.86 (54.443)	15.77 (70.248)
	95% CI of Geometric Mean	14.98, 21.22	15.64, 22.74	11.91, 20.89
	Median	20.15	19.01	16.46
	Q25, Q75	13.30, 26.93	12.93, 30.10	11.14, 21.02
	Min, Max	0.9, 79.3	6.4, 41.4	3.9, 45.7
	Mean (SD)	21.98 (13.630)	21.26 (10.329)	18.88 (11.596)
	95% CI of Mean	18.72, 25.23	17.47, 25.06	13.74, 24.03

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set**

Parameter (units): 4-ABP (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	5 (6.8)	0	0
	Geometric Mean (CV%)	9.12 (71.148)	18.09 (62.151)	8.79 (52.269)
	95% CI of Geometric Mean	7.86, 10.58	14.86, 22.02	7.11, 10.88
	Median	9.83	17.90	7.61
	Q25, Q75	6.68, 12.92	12.39, 31.74	7.18, 9.27
	Min, Max	1.0, 85.4	5.5, 55.9	4.5, 27.6
	Mean (SD)	11.21 (10.113)	21.21 (12.664)	10.09 (6.513)
	95% CI of Mean	8.86, 13.56	16.86, 25.57	7.27, 12.91

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set**

Parameter (units): 4-ABP (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	21 (28.4)	0	6 (26.1)
	Geometric Mean (CV%)	4.26 (83.777)	15.68 (73.585)	3.97 (63.163)
	95% CI of Geometric Mean	3.59, 5.04	12.51, 19.66	3.08, 5.10
	Median	4.78	15.77	3.93
	Q25, Q75	2.44, 6.78	11.34, 25.28	2.78, 5.17
	Min, Max	1.0, 34.9	4.4, 66.9	1.3, 12.7
	Mean (SD)	5.56 (4.905)	19.19 (12.813)	4.66 (2.856)
	95% CI of Mean	4.42, 6.70	14.78, 23.59	3.42, 5.90

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set**

Parameter (units): 4-ABP (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	25 (33.8)	0	9 (39.1)
	Geometric Mean (CV%)	3.53 (78.469)	19.34 (60.564)	3.48 (92.102)
	95% CI of Geometric Mean	3.00, 4.15	15.96, 23.44	2.47, 4.89
	Median	3.52	19.88	3.13
	Q25, Q75	2.19, 5.31	14.33, 28.70	1.73, 5.54
	Min, Max	0.8, 50.7	4.6, 67.6	1.1, 15.0
	Mean (SD)	4.75 (6.090)	22.28 (12.172)	4.71 (3.960)
	95% CI of Mean	3.34, 6.17	18.09, 26.47	2.99, 6.42

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set****Parameter (units): 4-ABP (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	40 (54.1)	0	15 (65.2)
	Geometric Mean (CV%)	2.71 (81.587)	17.06 (64.365)	2.26 (84.274)
	95% CI of Geometric Mean	2.29, 3.20	13.93, 20.89	1.64, 3.11
	Median	2.66	19.65	1.99
	Q25, Q75	1.61, 4.30	11.81, 27.15	1.30, 3.50
	Min, Max	0.6, 40.5	4.9, 46.7	0.6, 8.9
	Mean (SD)	3.74 (4.968)	19.85 (10.403)	2.97 (2.435)
	95% CI of Mean	2.58, 4.90	16.27, 23.43	1.91, 4.03

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set**

Parameter (units): 4-ABP (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	50 (67.6)	1 (2.9)	15 (65.2)
	Geometric Mean (CV%)	3.05 (68.162)	15.98 (70.107)	2.38 (63.611)
	95% CI of Geometric Mean	2.64, 3.52	12.85, 19.86	1.85, 3.07
	Median	2.88	17.66	1.94
	Q25, Q75	1.93, 4.08	10.29, 25.49	1.56, 3.80
	Min, Max	1.0, 25.4	2.2, 53.0	0.9, 8.3
	Mean (SD)	3.81 (3.462)	18.95 (10.812)	2.84 (1.924)
	95% CI of Mean	3.01, 4.62	15.23, 22.67	2.01, 3.68

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set**

Parameter (units): 4-ABP (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	38	30	12
	Missing, n (%)	2 (5.0)	4 (11.8)	1 (7.7)
	BLOQ, n(%)	1 (2.6)	0	0
	Geometric Mean (CV%)	16.72 (88.390)	18.09 (55.958)	17.61 (56.790)
	95% CI of Geometric Mean	13.02, 21.47	14.88, 21.99	12.58, 24.64
	Median	19.17	18.68	15.89
	Q25, Q75	13.31, 25.07	12.88, 26.93	12.49, 25.02
	Min, Max	0.9, 66.2	6.4, 41.4	7.9, 45.7
	Mean (SD)	20.60 (12.363)	20.51 (10.178)	20.17 (11.857)
	95% CI of Mean	16.53, 24.67	16.70, 24.31	12.63, 27.71

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set**

Parameter (units): 4-ABP (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Day 30	n	40	34	13
	BLOQ, n(%)	10 (25.0)	1 (2.9)	3 (23.1)
	Geometric Mean (CV%)	5.44 (110.523)	20.88 (66.943)	6.36 (113.049)
	95% CI of Geometric Mean	4.08, 7.24	16.88, 25.83	3.67, 11.01
	Median	5.37	20.08	7.01
	Q25, Q75	3.03, 10.51	14.05, 31.21	5.43, 12.10
	Min, Max	1.1, 27.6	3.9, 57.9	0.9, 22.9
	Mean (SD)	7.81 (6.812)	24.77 (14.663)	8.59 (6.118)
	95% CI of Mean	5.62, 9.99	19.65, 29.89	4.89, 12.30

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set**

Parameter (units): 4-ABP (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	37	31	12
	Missing, n (%)	2 (5.1)	4 (11.4)	0
	BLOQ, n(%)	1 (2.7)	0	0
	Geometric Mean (CV%)	18.33 (101.578)	17.91 (55.278)	14.54 (66.099)
	95% CI of Geometric Mean	13.84, 24.27	14.81, 21.64	9.91, 21.32
	Median	22.64	18.35	15.89
	Q25, Q75	13.36, 29.49	12.88, 26.93	11.01, 19.48
	Min, Max	0.9, 79.3	6.4, 41.4	3.9, 39.4
	Mean (SD)	23.64 (15.756)	20.27 (10.094)	16.92 (9.583)
	95% CI of Mean	18.38, 28.90	16.56, 23.98	10.83, 23.01

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set**

Parameter (units): 4-ABP (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Day 60	n	39	35	12
	BLOQ, n(%)	6 (15.4)	1 (2.9)	3 (25.0)
	Geometric Mean (CV%)	6.16 (89.204)	19.02 (85.282)	5.91 (115.028)
	95% CI of Geometric Mean	4.80, 7.90	14.75, 24.53	3.29, 10.59
	Median	6.06	20.67	6.79
	Q25, Q75	3.91, 9.16	13.56, 35.37	3.25, 8.48
	Min, Max	1.5, 32.7	1.6, 48.8	1.2, 28.9
	Mean (SD)	8.35 (7.620)	23.50 (13.642)	8.51 (7.991)
	95% CI of Mean	5.87, 10.82	18.81, 28.19	3.43, 13.59

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set**

Parameter (units): 4-ABP (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	45	29	9
	Missing, n (%)	2 (4.3)	3 (9.4)	0
	BLOQ, n(%)	1 (2.2)	0	0
	Geometric Mean (CV%)	18.23 (93.916)	17.36 (54.436)	12.50 (63.643)
	95% CI of Geometric Mean	14.35, 23.15	14.30, 21.08	7.98, 19.58
	Median	21.70	18.20	13.12
	Q25, Q75	13.36, 29.49	12.88, 25.20	10.17, 16.01
	Min, Max	0.9, 79.3	6.4, 40.0	3.9, 29.0
	Mean (SD)	23.10 (15.157)	19.59 (9.631)	14.31 (7.426)
	95% CI of Mean	18.54, 27.66	15.92, 23.25	8.59, 20.02

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.1 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - PP Set**

Parameter (units): 4-ABP (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Day 90	n	47	32	9
	BLOQ, n(%)	11 (23.4)	1 (3.1)	4 (44.4)
	Geometric Mean (CV%)	6.29 (110.397)	18.77 (77.990)	5.11 (162.890)
	95% CI of Geometric Mean	4.83, 8.18	14.64, 24.07	2.12, 12.25
	Median	5.81	19.71	4.58
	Q25, Q75	3.49, 12.23	11.58, 32.57	2.10, 14.07
	Min, Max	1.3, 41.7	2.1, 47.7	1.0, 22.5
	Mean (SD)	9.24 (8.889)	22.60 (12.248)	8.32 (7.633)
	95% CI of Mean	6.63, 11.86	18.18, 27.02	2.44, 14.19

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		36		36	
	Missing, n (%)	9 (11.3)		5 (12.2)		3 (7.7)	
	BLOQ, n(%)	2 (2.8)		0		0	
	Geometric Mean (CV%)	10.88 (81.074)		11.99 (62.482)		10.83 (67.664)	
	95% CI of Geometric Mean	9.19, 12.88		9.86, 14.56		8.80, 13.34	
	Median	12.16		11.51		11.04	
	Q25, Q75	7.97, 15.74		8.51, 16.88		8.24, 14.14	
	Min, Max	0.4, 58.8		4.2, 47.8		2.6, 42.4	
	Mean (SD)	13.17 (8.338)		14.15 (9.113)		12.97 (8.439)	
	95% CI of Mean	11.20, 15.15		11.06, 17.24		10.11, 15.83	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	5 (6.5)		0		0	
	Geometric Mean (CV%)	5.52 (79.550)		11.40 (68.503)		6.13 (65.591)	
	95% CI of Geometric Mean	4.70, 6.48		9.35, 13.91		5.01, 7.48	
	Median	5.67	-51.48	11.37	-0.50	5.50	-44.14
	Q25, Q75	3.92, 8.09	-58.05, -35.63	7.32, 16.80	-19.60, 22.26	3.93, 9.12	-60.32, -24.28
	Min, Max	0.4, 41.3	-81.0, 39.6	3.4, 47.8	-53.4, 107.5	1.7, 25.4	-83.5, 67.0
	Mean (SD)	6.91 (5.698)	-43.63 (25.110)	13.80 (9.348)	4.31 (32.546)	7.42 (5.450)	-37.06 (31.272)
	95% CI of Mean	5.61, 8.21	-49.58, -37.68	10.80, 16.79	-6.70, 15.33	5.60, 9.24	-47.64, -26.47

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	22 (28.6)		0		8 (21.6)	
	Geometric Mean (CV%)	2.54 (88.703)		10.01 (78.074)		3.14 (106.622)	
	95% CI of Geometric Mean	2.13, 3.03		8.02, 12.48		2.34, 4.20	
	Median	2.46	-75.05	10.47	-13.88	3.01	-69.55
	Q25, Q75	1.58, 4.40	-83.59, -64.99	6.13, 16.72	-34.99, 4.95	1.59, 5.73	-82.27, -51.57
	Min, Max	0.5, 18.4	-92.5, 43.6	2.4, 47.8	-70.2, 196.6	0.7, 18.1	-92.8, 0.0
	Mean (SD)	3.41 (3.029)	-71.11 (20.681)	12.52 (8.988)	-4.43 (48.411)	4.52 (4.091)	-61.12 (28.950)
	95% CI of Mean	2.71, 4.10	-76.01, -66.21	9.64, 15.40	-20.81, 11.96	3.15, 5.89	-70.92, -51.32

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	27 (35.1)		0		10 (27.0)	
	Geometric Mean (CV%)	2.09 (86.859)		12.01 (67.265)		3.01 (119.173)	
	95% CI of Geometric Mean	1.75, 2.48		9.87, 14.60		2.19, 4.12	
	Median	2.05	-80.67	11.53	3.54	2.34	-78.96
	Q25, Q75	1.28, 3.05	-87.92, -73.47	8.63, 17.69	-14.00, 31.81	1.56, 7.93	-86.88, -35.27
	Min, Max	0.6, 25.7	-96.6, 384.2	3.4, 47.8	-56.3, 83.2	0.7, 18.1	-93.4, 23.5
	Mean (SD)	2.92 (3.484)	-71.46 (56.762)	14.43 (9.658)	6.93 (32.961)	4.59 (4.315)	-59.19 (35.758)
	95% CI of Mean	2.12, 3.72	-84.90, -58.02	11.34, 17.52	-4.22, 18.09	3.15, 6.04	-71.29, -47.08

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	41 (53.2)		0		17 (45.9)	
	Geometric Mean (CV%)	1.62 (82.720)		10.88 (61.733)		2.11 (130.230)	
	95% CI of Geometric Mean	1.37, 1.91		9.06, 13.05		1.51, 2.95	
	Median	1.43	-85.15	11.81	-1.15	2.02	-85.07
	Q25, Q75	1.07, 2.23	-92.20, -75.84	7.67, 15.60	-34.27, 25.98	0.91, 4.05	-90.16, -49.99
	Min, Max	0.3, 19.2	-98.1, 32.2	3.4, 47.8	-57.0, 77.1	0.3, 18.1	-95.3, 0.0
	Mean (SD)	2.22 (2.607)	-78.95 (21.683)	12.70 (7.851)	2.79 (39.106)	3.50 (3.984)	-68.43 (32.236)
	95% CI of Mean	1.63, 2.82	-84.09, -73.82	10.18, 15.21	-10.45, 16.03	2.16, 4.83	-79.34, -57.52

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	53 (68.8)		2 (5.0)		19 (51.4)	
	Geometric Mean (CV%)	1.79 (77.185)		9.95 (78.759)		2.06 (115.434)	
	95% CI of Geometric Mean	1.53, 2.09		7.96, 12.43		1.51, 2.81	
	Median	1.73	-86.46	10.12	-8.51	1.79	-85.39
	Q25, Q75	1.14, 2.60	-90.73, -70.67	6.82, 15.52	-27.83, 7.33	1.22, 3.60	-90.06, -64.69
	Min, Max	0.6, 17.3	-95.5, 207.8	1.5, 47.8	-77.3, 79.2	0.5, 18.1	-97.1, 0.0
	Mean (SD)	2.36 (2.410)	-74.15 (40.109)	12.36 (8.718)	-7.60 (35.556)	3.29 (3.914)	-69.69 (31.846)
	95% CI of Mean	1.81, 2.91	-83.65, -64.65	9.56, 15.15	-19.64, 4.43	1.98, 4.60	-80.47, -58.91

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	12 (15.6)		1 (2.5)		5 (13.5)	
	Geometric Mean (CV%)	4.47 (101.601)		13.30 (76.310)		5.28 (116.729)	
	95% CI of Geometric Mean	3.69, 5.42		10.71, 16.53		3.87, 7.20	
	Median	4.97	-53.82	13.63	9.47	5.70	-51.54
	Q25, Q75	2.92, 8.18	-77.60, -26.00	9.05, 22.18	-9.46, 63.23	3.18, 9.64	-70.54, 0.00
	Min, Max	0.5, 25.4	-98.6, 90.7	2.0, 47.8	-57.4, 178.8	0.5, 45.8	-94.7, 63.5
	Mean (SD)	6.06 (4.744)	-45.32 (41.268)	16.38 (10.733)	26.80 (55.592)	7.75 (8.044)	-37.82 (42.034)
	95% CI of Mean	4.98, 7.15	-55.09, -35.55	12.94, 19.82	7.99, 45.62	5.07, 10.44	-52.05, -23.59

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	10 (13.0)		1 (2.5)		2 (5.4)	
	Geometric Mean (CV%)	4.55 (102.654)		12.34 (90.345)		6.07 (81.296)	
	95% CI of Geometric Mean	3.75, 5.52		9.63, 15.80		4.78, 7.70	
	Median	4.74	-59.37	14.23	19.35	6.92	-43.46
	Q25, Q75	2.90, 7.56	-77.55, -28.95	6.79, 21.85	-22.53, 45.94	4.11, 9.37	-61.67, -10.03
	Min, Max	0.5, 35.2	-96.6, 448.7	1.4, 47.8	-82.5, 181.8	1.1, 26.8	-87.5, 156.2
	Mean (SD)	6.33 (5.695)	-35.73 (79.999)	15.83 (10.572)	21.11 (57.846)	7.58 (5.214)	-33.59 (45.484)
	95% CI of Mean	5.03, 7.63	-54.67, -16.79	12.45, 19.22	1.54, 40.69	5.84, 9.33	-48.98, -18.19

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	16 (20.8)		1 (2.5)		5 (13.5)	
	Geometric Mean (CV%)	4.22 (121.934)		12.53 (82.184)		5.81 (103.833)	
	95% CI of Geometric Mean	3.39, 5.24		9.96, 15.77		4.36, 7.73	
	Median	5.03	-57.98	12.92	14.74	6.68	-43.02
	Q25, Q75	2.43, 7.59	-77.55, -21.12	8.16, 21.60	-13.12, 43.53	4.23, 10.88	-65.69, -2.85
	Min, Max	0.6, 41.8	-98.6, 165.7	1.7, 47.8	-78.5, 178.8	0.9, 23.2	-90.2, 134.8
	Mean (SD)	6.48 (7.223)	-44.34 (52.488)	15.62 (10.156)	22.71 (52.242)	7.78 (5.481)	-35.02 (43.946)
	95% CI of Mean	4.84, 8.13	-56.77, -31.92	12.37, 18.87	5.03, 40.40	5.95, 9.62	-49.90, -20.15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	74	37	37
	Missing, n (%)	6 (7.5)	4 (9.8)	2 (5.1)
	BLOQ, n(%)	2 (2.7)	0	0
	Geometric Mean (CV%)	18.03 (81.746)	19.56 (56.870)	17.73 (63.295)
	95% CI of Geometric Mean	15.28, 21.29	16.39, 23.34	14.61, 21.53
	Median	20.95	20.37	17.48
	Q25, Q75	13.30, 26.93	13.14, 31.74	13.05, 27.50
	Min, Max	0.9, 79.3	6.4, 41.8	3.9, 54.6
	Mean (SD)	22.04 (13.336)	22.22 (10.858)	20.70 (11.752)
	95% CI of Mean	18.94, 25.13	18.59, 25.84	16.77, 24.62

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 1	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	5 (6.4)	0	0
	Geometric Mean (CV%)	9.18 (69.205)	18.75 (59.587)	10.00 (55.899)
	95% CI of Geometric Mean	7.96, 10.57	15.75, 22.32	8.42, 11.88
	Median	9.83	18.06	8.37
	Q25, Q75	6.71, 12.92	12.77, 31.74	7.35, 13.78
	Min, Max	1.0, 85.4	5.5, 55.9	4.5, 40.4
	Mean (SD)	11.17 (9.862)	21.69 (12.079)	11.63 (7.592)
	95% CI of Mean	8.94, 13.40	17.87, 25.51	9.13, 14.13

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 2	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	22 (28.2)	0	8 (21.1)
	Geometric Mean (CV%)	4.27 (82.297)	16.54 (71.143)	5.14 (91.113)
	95% CI of Geometric Mean	3.62, 5.02	13.51, 20.24	3.98, 6.64
	Median	4.68	16.95	4.79
	Q25, Q75	2.47, 6.78	11.54, 26.76	2.91, 8.99
	Min, Max	1.0, 34.9	4.4, 66.9	1.3, 40.4
	Mean (SD)	5.54 (4.827)	19.94 (12.459)	7.14 (7.340)
	95% CI of Mean	4.45, 6.63	16.01, 23.88	4.72, 9.56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 3	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	27 (34.6)	0	11 (28.9)
	Geometric Mean (CV%)	3.48 (78.516)	19.74 (59.939)	4.67 (110.760)
	95% CI of Geometric Mean	2.97, 4.08	16.57, 23.52	3.47, 6.27
	Median	3.52	21.20	4.24
	Q25, Q75	2.14, 5.31	14.58, 28.70	2.32, 9.65
	Min, Max	0.8, 50.7	4.6, 67.6	1.1, 40.4
	Mean (SD)	4.68 (5.954)	22.62 (11.784)	7.05 (7.625)
	95% CI of Mean	3.33, 6.03	18.90, 26.35	4.54, 9.56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 4	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	41 (52.6)	0	18 (47.4)
	Geometric Mean (CV%)	2.71 (79.409)	17.67 (60.269)	3.31 (126.246)
	95% CI of Geometric Mean	2.31, 3.18	14.81, 21.06	2.39, 4.56
	Median	2.66	20.47	2.53
	Q25, Q75	1.65, 4.27	11.98, 27.01	1.64, 6.28
	Min, Max	0.6, 40.5	4.9, 46.7	0.6, 40.4
	Mean (SD)	3.70 (4.846)	20.20 (9.804)	5.65 (7.638)
	95% CI of Mean	2.60, 4.79	17.10, 23.30	3.13, 8.16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 5	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	53 (67.9)	2 (4.9)	20 (52.6)
	Geometric Mean (CV%)	3.08 (68.031)	16.56 (77.895)	3.44 (109.107)
	95% CI of Geometric Mean	2.68, 3.55	13.32, 20.58	2.57, 4.61
	Median	2.88	18.30	3.05
	Q25, Q75	1.95, 4.76	10.46, 27.63	1.78, 5.22
	Min, Max	1.0, 25.4	2.2, 53.0	0.9, 40.4
	Mean (SD)	3.85 (3.423)	20.06 (11.375)	5.55 (7.558)
	95% CI of Mean	3.07, 4.62	16.46, 23.65	3.07, 8.04

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	12 (15.4)	1 (2.4)	6 (15.8)
	Geometric Mean (CV%)	7.26 (99.087)	21.08 (70.808)	8.32 (115.806)
	95% CI of Geometric Mean	6.02, 8.75	17.23, 25.79	6.14, 11.28
	Median	7.88	21.56	9.45
	Q25, Q75	4.50, 13.03	14.12, 34.58	5.37, 15.07
	Min, Max	1.1, 31.8	3.9, 57.9	0.9, 48.2
	Mean (SD)	9.73 (7.172)	25.14 (14.365)	12.05 (11.071)
	95% CI of Mean	8.11, 11.36	20.60, 29.68	8.40, 15.69

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	10 (12.8)	1 (2.4)	3 (7.9)
	Geometric Mean (CV%)	7.36 (104.332)	20.11 (80.715)	9.79 (90.819)
	95% CI of Geometric Mean	6.06, 8.93	16.08, 25.16	7.58, 12.64
	Median	7.27	21.00	9.22
	Q25, Q75	4.36, 11.97	13.76, 37.95	6.92, 15.31
	Min, Max	1.0, 62.4	1.6, 48.8	1.2, 56.9
	Mean (SD)	10.51 (10.139)	24.39 (13.323)	12.91 (10.851)
	95% CI of Mean	8.21, 12.80	20.18, 28.60	9.34, 16.48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.9.2 Descriptive Statistics of 4-ABP in 24-hour Urine Collection - FAS****Parameter (units): 4-ABP (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	16 (20.5)	1 (2.4)	6 (15.8)
	Geometric Mean (CV%)	7.06 (112.536)	19.85 (72.607)	9.06 (112.418)
	95% CI of Geometric Mean	5.75, 8.66	16.16, 24.38	6.73, 12.20
	Median	6.73	20.67	11.49
	Q25, Q75	4.01, 13.04	12.66, 31.98	6.09, 16.53
	Min, Max	1.0, 44.2	2.1, 48.8	1.0, 40.4
	Mean (SD)	10.24 (9.161)	23.45 (12.080)	12.47 (9.103)
	95% CI of Mean	8.17, 12.31	19.64, 27.27	9.48, 15.47

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		30		21	
	Missing, n (%)	8 (10.7)		5 (14.3)		3 (12.5)	
	Geometric Mean (CV%)	61.36 (68.101)		62.93 (60.557)		56.16 (78.155)	
	95% CI of Geometric Mean	52.78, 71.33		51.07, 77.54		41.01, 76.91	
	Median	68.16		63.18		57.96	
	Q25, Q75	51.29, 84.78		42.98, 87.28		33.55, 86.21	
	Min, Max	6.1, 409.8		20.3, 220.5		10.7, 156.7	
	Mean (SD)	72.87 (51.438)		73.56 (45.938)		68.78 (42.543)	
	95% CI of Mean	60.32, 85.42		56.40, 90.71		49.41, 88.15	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	2 (2.7)		0		1 (4.5)	
	Geometric Mean (CV%)	12.29 (73.244)		60.16 (65.384)		12.16 (73.432)	
	95% CI of Geometric Mean	10.54, 14.32		48.85, 74.09		9.08, 16.27	
	Median	11.98	-80.29	57.32	-2.97	11.42	-79.20
	Q25, Q75	8.95, 17.95	-84.52, -76.11	45.40, 90.57	-26.63, 14.50	8.44, 16.60	-82.75, -74.48
	Min, Max	1.5, 144.7	-93.5, 0.0	16.2, 220.5	-44.1, 111.5	2.8, 45.0	-87.0, -14.9
	Mean (SD)	15.68 (17.399)	-77.90 (12.495)	71.70 (46.486)	3.99 (37.040)	15.04 (11.180)	-76.10 (14.849)
	95% CI of Mean	11.62, 19.75	-80.95, -74.85	55.48, 87.93	-9.85, 17.82	10.07, 20.00	-82.86, -69.33

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	10 (13.7)		0		4 (18.2)	
	Geometric Mean (CV%)	5.77 (70.498)		57.94 (80.373)		5.30 (95.489)	
	95% CI of Geometric Mean	4.97, 6.70		45.28, 74.12		3.71, 7.58	
	Median	5.98	-89.94	62.32	-8.63	5.10	-90.09
	Q25, Q75	4.10, 8.68	-93.22, -87.44	37.24, 96.24	-25.67, 29.19	3.38, 9.02	-93.24, -85.62
	Min, Max	0.9, 27.9	-97.4, -64.6	11.9, 220.5	-68.3, 307.5	1.2, 25.1	-97.8, -57.5
	Mean (SD)	7.02 (4.946)	-89.52 (5.030)	71.93 (46.633)	11.91 (76.871)	7.18 (6.242)	-88.19 (8.766)
	95% CI of Mean	5.86, 8.18	-90.75, -88.29	55.66, 88.21	-16.80, 40.62	4.41, 9.95	-92.18, -84.19

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	20 (27.4)		0		4 (18.2)	
	Geometric Mean (CV%)	3.89 (66.959)		68.46 (60.020)		4.93 (103.399)	
	95% CI of Geometric Mean	3.37, 4.49		56.41, 83.08		3.37, 7.20	
	Median	3.88	-93.58	63.64	2.85	4.28	-92.44
	Q25, Q75	2.60, 5.68	-95.97, -90.49	52.68, 91.02	-15.13, 31.35	3.31, 6.05	-95.50, -87.13
	Min, Max	0.8, 16.3	-97.9, -74.8	19.9, 250.0	-44.5, 167.7	1.5, 64.6	-98.1, 66.5
	Mean (SD)	4.64 (2.906)	-92.48 (4.879)	79.85 (49.941)	18.31 (50.370)	8.11 (13.268)	-82.95 (35.004)
	95% CI of Mean	3.95, 5.32	-93.67, -91.28	62.42, 97.28	-0.51, 37.12	2.22, 14.00	-98.89, -67.02

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	27 (37.0)		0		8 (36.4)	
	Geometric Mean (CV%)	3.20 (71.978)		60.72 (57.053)		3.05 (70.357)	
	95% CI of Geometric Mean	2.75, 3.73		50.45, 73.08		2.30, 4.05	
	Median	3.15	-95.17	60.09	-1.31	2.89	-94.91
	Q25, Q75	1.99, 4.62	-96.68, -91.92	46.51, 87.82	-25.43, 32.08	1.74, 4.81	-95.92, -93.17
	Min, Max	0.8, 40.0	-99.0, -5.8	22.1, 220.5	-44.1, 114.6	1.1, 10.6	-98.3, -74.3
	Mean (SD)	4.14 (4.791)	-92.73 (11.493)	69.59 (39.470)	8.84 (45.068)	3.73 (2.651)	-93.02 (5.737)
	95% CI of Mean	3.02, 5.26	-95.54, -89.93	55.81, 83.36	-7.99, 25.67	2.55, 4.91	-95.64, -90.41

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	58 (79.5)		0		16 (72.7)	
	Geometric Mean (CV%)	2.51 (64.276)		63.05 (60.899)		2.17 (79.665)	
	95% CI of Geometric Mean	2.18, 2.89		51.83, 76.71		1.58, 2.97	
	Median	2.50	-96.08	63.24	4.42	2.04	-97.42
	Q25, Q75	1.83, 3.64	-97.58, -94.41	45.68, 96.09	-18.13, 22.24	1.26, 2.98	-98.00, -93.87
	Min, Max	0.6, 17.6	-98.7, -62.1	14.7, 220.5	-63.6, 216.0	0.8, 12.6	-99.2, -76.1
	Mean (SD)	3.01 (2.295)	-94.30 (5.911)	73.07 (41.798)	13.02 (54.708)	2.86 (2.699)	-94.00 (6.471)
	95% CI of Mean	2.47, 3.55	-95.75, -92.85	58.48, 87.66	-7.41, 33.45	1.66, 4.06	-96.95, -91.05

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		29		12	
	Missing, n (%)	3 (7.5)		5 (14.7)		1 (7.7)	
	Geometric Mean (CV%)	61.28 (72.296)		59.39 (55.945)		63.64 (65.557)	
	95% CI of Geometric Mean	49.36, 76.08		48.69, 72.44		43.52, 93.06	
	Median	68.26		63.11		57.39	
	Q25, Q75	51.27, 83.01		40.06, 82.26		39.03, 110.97	
	Min, Max	6.1, 409.8		20.3, 177.6		26.5, 156.7	
	Mean (SD)	74.72 (62.447)		67.78 (37.630)		74.76 (44.046)	
	95% CI of Mean	53.89, 95.54		53.46, 82.10		46.77, 102.75	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	37	33	29	13	12
	Missing, n (%)	0	3 (7.5)	1 (2.9)	5 (14.7)	0	1 (7.7)
	BLOQ, n(%)	9 (22.5)		0		3 (23.1)	
	Geometric Mean (CV%)	7.74 (133.235)		61.20 (56.064)		7.65 (143.613)	
	95% CI of Geometric Mean	5.60, 10.69		50.84, 73.67		4.03, 14.50	
	Median	8.00	-86.86	62.66	5.85	9.17	-86.41
	Q25, Q75	3.47, 17.30	-94.41, -71.78	40.90, 84.55	-20.04, 36.16	3.59, 18.48	-90.88, -80.91
	Min, Max	1.5, 54.2	-98.3, 11.1	23.3, 145.2	-59.3, 133.7	1.0, 27.7	-98.3, -14.6
	Mean (SD)	12.51 (12.967)	-78.25 (25.593)	69.69 (36.020)	14.17 (49.273)	11.58 (9.247)	-81.31 (22.070)
	95% CI of Mean	8.36, 16.67	-86.79, -69.71	56.91, 82.47	-4.57, 32.92	5.98, 17.17	-95.34, -67.29

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	35		30		11	
	Missing, n (%)	4 (10.3)		5 (14.3)		1 (8.3)	
	Geometric Mean (CV%)	60.80 (81.992)		59.38 (54.837)		48.90 (85.691)	
	95% CI of Geometric Mean	47.52, 77.78		49.03, 71.92		29.70, 80.51	
	Median	70.07		61.13		55.37	
	Q25, Q75	51.29, 84.78		40.06, 82.26		30.71, 94.16	
	Min, Max	6.1, 409.8		20.3, 177.6		10.7, 134.5	
	Mean (SD)	76.28 (64.666)		67.49 (37.010)		61.14 (40.850)	
	95% CI of Mean	54.06, 98.50		53.67, 81.32		33.69, 88.59	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	35	34	30	11	11
	Missing, n (%)	0	4 (10.3)	1 (2.9)	5 (14.3)	1 (8.3)	1 (8.3)
	BLOQ, n(%)	10 (25.6)		0		3 (27.3)	
	Geometric Mean (CV%)	6.96 (130.822)		59.13 (69.506)		7.62 (196.388)	
	95% CI of Geometric Mean	5.03, 9.63		47.49, 73.61		3.27, 17.73	
	Median	7.26	-89.00	65.81	4.56	9.51	-84.53
	Q25, Q75	4.01, 16.41	-94.62, -76.47	42.01, 89.85	-13.38, 36.16	2.71, 15.65	-92.75, -72.44
	Min, Max	0.9, 45.7	-98.0, -40.8	10.8, 160.9	-55.6, 141.3	1.2, 57.9	-97.9, 43.7
	Mean (SD)	10.73 (10.116)	-85.41 (12.706)	69.86 (38.301)	13.20 (42.882)	15.05 (18.728)	-72.19 (40.043)
	95% CI of Mean	7.45, 14.01	-89.78, -81.04	56.49, 83.23	-2.81, 29.22	2.47, 27.64	-99.10, -45.29

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	43		29		9	
	Missing, n (%)	4 (8.5)		3 (9.4)		0	
	Geometric Mean (CV%)	63.50 (75.587)		59.73 (55.823)		43.10 (84.659)	
	95% CI of Geometric Mean	51.63, 78.11		48.99, 72.82		24.49, 75.84	
	Median	70.07		63.11		44.52	
	Q25, Q75	52.19, 86.17		40.06, 82.26		30.71, 57.96	
	Min, Max	6.1, 409.8		20.3, 177.6		10.7, 127.8	
	Mean (SD)	77.46 (59.940)		68.09 (37.518)		53.63 (36.679)	
	95% CI of Mean	59.01, 95.91		53.81, 82.37		25.43, 81.83	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	43	32	29	9	9
	Missing, n (%)	0	4 (8.5)	0	3 (9.4)	0	
	BLOQ, n(%)	7 (14.9)		0		4 (44.4)	
	Geometric Mean (CV%)	9.64 (119.736)		59.69 (71.451)		5.90 (190.677)	
	95% CI of Geometric Mean	7.31, 12.72		47.34, 75.24		2.27, 15.30	
	Median	12.12	-82.23	68.54	8.95	7.82	-85.87
	Q25, Q75	4.06, 18.54	-93.77, -69.33	44.16, 90.48	-14.43, 27.16	1.51, 19.89	-89.56, -65.61
	Min, Max	1.0, 71.0	-99.4, 54.3	9.1, 147.5	-62.5, 178.2	1.3, 20.7	-98.4, -32.7
	Mean (SD)	14.01 (12.543)	-77.41 (25.267)	70.37 (36.221)	14.16 (54.806)	10.23 (8.885)	-77.53 (20.714)
	95% CI of Mean	10.33, 17.70	-85.19, -69.62	57.31, 83.44	-6.69, 35.01	3.39, 17.06	-93.46, -61.61

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	70	31	22
	Missing, n (%)	5 (6.7)	4 (11.4)	2 (8.3)
	Geometric Mean (CV%)	101.31 (67.594)	101.65 (59.180)	90.95 (76.148)
	95% CI of Geometric Mean	87.52, 117.28	83.14, 124.29	67.38, 122.76
	Median	105.06	101.80	113.43
	Q25, Q75	79.37, 140.42	74.94, 143.08	66.55, 143.76
	Min, Max	15.1, 461.5	25.4, 224.4	15.9, 229.6
	Mean (SD)	120.24 (75.155)	115.52 (55.132)	108.50 (57.403)
	95% CI of Mean	102.32, 138.17	95.30, 135.75	83.04, 133.95

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	2 (2.7)	0	1 (4.3)
	Geometric Mean (CV%)	20.16 (53.815)	99.07 (62.759)	19.27 (61.037)
	95% CI of Geometric Mean	17.93, 22.66	81.28, 120.77	15.10, 24.59
	Median	20.74	95.68	18.02
	Q25, Q75	15.56, 27.68	70.88, 156.37	14.56, 26.54
	Min, Max	4.4, 91.7	25.1, 307.4	3.7, 50.4
	Mean (SD)	22.72 (12.130)	115.31 (64.302)	22.16 (12.113)
	95% CI of Mean	19.91, 25.54	93.21, 137.40	16.92, 27.40

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	10 (13.5)	0	4 (17.4)
	Geometric Mean (CV%)	9.62 (62.954)	95.96 (80.261)	8.34 (67.656)
	95% CI of Geometric Mean	8.41, 11.00	75.31, 122.27	6.39, 10.88
	Median	10.00	105.83	8.15
	Q25, Q75	7.22, 13.64	66.96, 154.81	6.25, 12.50
	Min, Max	1.8, 51.1	21.2, 386.2	2.1, 26.6
	Mean (SD)	11.36 (7.734)	118.67 (75.363)	9.93 (6.241)
	95% CI of Mean	9.56, 13.15	92.77, 144.56	7.23, 12.63

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	20 (27.0)	0	5 (21.7)
	Geometric Mean (CV%)	6.46 (63.125)	112.69 (58.726)	7.32 (89.434)
	95% CI of Geometric Mean	5.64, 7.39	93.47, 135.87	5.25, 10.21
	Median	6.54	120.26	6.05
	Q25, Q75	4.37, 9.66	78.42, 178.30	5.14, 9.28
	Min, Max	1.4, 19.2	19.7, 387.3	1.9, 99.0
	Mean (SD)	7.55 (4.220)	128.53 (67.719)	11.38 (19.483)
	95% CI of Mean	6.57, 8.53	105.26, 151.80	2.95, 19.81

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	27 (36.5)	0	9 (39.1)
	Geometric Mean (CV%)	5.35 (66.928)	98.31 (56.689)	4.63 (56.489)
	95% CI of Geometric Mean	4.64, 6.16	82.00, 117.86	3.68, 5.82
	Median	5.33	103.27	4.07
	Q25, Q75	3.27, 7.39	65.37, 140.12	2.96, 6.67
	Min, Max	1.6, 63.4	24.5, 250.5	2.2, 12.6
	Mean (SD)	6.74 (7.472)	111.24 (53.637)	5.34 (3.174)
	95% CI of Mean	5.01, 8.48	92.81, 129.67	3.96, 6.71

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	59 (79.7)	0	17 (73.9)
	Geometric Mean (CV%)	4.29 (57.434)	104.24 (64.972)	3.59 (58.314)
	95% CI of Geometric Mean	3.78, 4.86	85.01, 127.82	2.84, 4.55
	Median	4.38	121.51	3.14
	Q25, Q75	3.15, 5.42	73.32, 159.85	2.59, 5.56
	Min, Max	1.3, 30.8	17.7, 318.9	1.6, 11.7
	Mean (SD)	5.02 (3.794)	121.53 (65.705)	4.18 (2.629)
	95% CI of Mean	4.14, 5.91	98.96, 144.11	3.04, 5.32

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (ng)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	38	30	12
	Missing, n (%)	2 (5.0)	4 (11.8)	1 (7.7)
	Geometric Mean (CV%)	99.25 (69.188)	99.36 (59.389)	99.71 (50.960)
	95% CI of Geometric Mean	80.80, 121.90	80.92, 122.00	73.47, 135.31
	Median	103.27	101.28	101.15
	Q25, Q75	79.37, 143.16	72.00, 142.11	69.08, 138.74
	Min, Max	15.1, 461.5	25.4, 224.4	42.8, 229.6
	Mean (SD)	118.49 (77.871)	113.14 (55.073)	110.70 (53.476)
	95% CI of Mean	92.89, 144.09	92.57, 133.71	76.72, 144.68

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (ng)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Day 30	n	40	34	13
	BLOQ, n(%)	9 (22.5)	0	3 (23.1)
	Geometric Mean (CV%)	12.54 (149.762)	102.57 (51.569)	12.57 (140.796)
	95% CI of Geometric Mean	8.86, 17.74	86.58, 121.51	6.68, 23.64
	Median	13.78	106.34	15.02
	Q25, Q75	6.19, 28.37	77.55, 135.88	9.32, 24.33
	Min, Max	1.6, 93.9	30.4, 283.1	1.6, 50.5
	Mean (SD)	20.96 (22.162)	114.41 (54.643)	18.18 (13.517)
	95% CI of Mean	13.87, 28.06	95.34, 133.48	10.01, 26.36

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (ng)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	37	31	12
	Missing, n (%)	2 (5.1)	4 (11.4)	0
	Geometric Mean (CV%)	98.14 (80.132)	98.65 (58.418)	81.49 (77.031)
	95% CI of Geometric Mean	77.60, 124.12	80.86, 120.35	52.81, 125.74
	Median	105.92	100.77	79.83
	Q25, Q75	70.97, 159.48	72.00, 142.11	66.55, 130.14
	Min, Max	15.1, 461.5	25.4, 224.4	15.9, 229.6
	Mean (SD)	121.45 (81.823)	112.06 (54.480)	97.39 (56.285)
	95% CI of Mean	94.17, 148.74	92.07, 132.05	61.62, 133.16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (ng)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Day 60	n	39	35	12
	BLOQ, n(%)	10 (25.6)	0	3 (25.0)
	Geometric Mean (CV%)	11.31 (129.649)	99.50 (73.379)	12.80 (181.444)
	95% CI of Geometric Mean	8.19, 15.61	79.41, 124.67	5.94, 27.56
	Median	9.96	108.78	13.79
	Q25, Q75	6.70, 24.30	78.98, 150.74	6.65, 22.97
	Min, Max	1.9, 79.8	11.8, 253.8	1.8, 104.7
	Mean (SD)	18.10 (19.227)	117.45 (60.743)	24.36 (31.374)
	95% CI of Mean	11.87, 24.34	96.58, 138.32	4.42, 44.30

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (ng)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	45	29	9
	Missing, n (%)	2 (4.3)	3 (9.4)	0
	Geometric Mean (CV%)	101.42 (75.679)	97.72 (58.979)	69.90 (77.173)
	95% CI of Geometric Mean	82.85, 124.15	79.38, 120.30	41.33, 118.22
	Median	105.92	100.77	71.60
	Q25, Q75	80.03, 144.41	74.94, 141.11	66.54, 126.54
	Min, Max	15.1, 461.5	25.4, 224.4	15.9, 143.8
	Mean (SD)	124.05 (83.593)	111.17 (54.469)	82.59 (43.303)
	95% CI of Mean	98.93, 149.17	90.44, 131.89	49.30, 115.88

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.1 Descriptive Statistics of 1-NA in 24-hour Urine Collection - PP Set****Parameter (units): 1-NA (ng)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Day 90	n	47	32	9
	BLOQ, n(%)	7 (14.9)	0	4 (44.4)
	Geometric Mean (CV%)	16.18 (122.072)	99.10 (70.855)	10.11 (197.929)
	95% CI of Geometric Mean	12.22, 21.42	78.73, 124.72	3.83, 26.67
	Median	21.78	112.38	15.98
	Q25, Q75	7.44, 30.08	67.30, 160.32	3.17, 31.15
	Min, Max	2.4, 96.9	10.9, 229.4	1.7, 42.2
	Mean (SD)	23.54 (19.745)	115.88 (57.409)	17.55 (15.612)
	95% CI of Mean	17.74, 29.35	95.17, 136.58	5.55, 29.56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		36		36	
	Missing, n (%)	9 (11.3)		5 (12.2)		3 (7.7)	
	Geometric Mean (CV%)	61.46 (65.906)		66.75 (60.097)		63.00 (69.277)	
	95% CI of Geometric Mean	53.31, 70.85		55.31, 80.55		50.97, 77.87	
	Median	68.05		65.75		71.44	
	Q25, Q75	52.19, 83.01		44.50, 94.67		43.82, 105.95	
	Min, Max	6.1, 409.8		20.3, 220.5		10.7, 156.7	
	Mean (SD)	72.37 (50.055)		77.49 (45.202)		74.12 (38.573)	
	95% CI of Mean	60.52, 84.22		62.19, 92.79		61.06, 87.17	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	2 (2.6)		0		1 (2.7)	
	Geometric Mean (CV%)	12.35 (71.825)		62.94 (61.656)		15.62 (113.725)	
	95% CI of Geometric Mean	10.66, 14.30		52.49, 75.48		11.52, 21.17	
	Median	11.98	-80.29	60.16	-2.97	12.72	-79.04
	Q25, Q75	9.21, 17.95	-84.27, -76.11	46.56, 93.83	-24.97, 13.65	8.44, 24.24	-83.99, -71.91
	Min, Max	1.5, 144.7	-93.5, 0.0	16.2, 220.5	-47.5, 111.5	2.8, 115.0	-93.6, 0.0
	Mean (SD)	15.64 (17.011)	-77.89 (12.223)	73.48 (43.550)	2.32 (35.238)	24.53 (28.290)	-67.05 (29.901)
	95% CI of Mean	11.77, 19.50	-80.79, -74.99	59.55, 87.42	-9.61, 14.25	15.10, 33.97	-77.18, -56.93

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	11 (14.3)		0		4 (10.8)	
	Geometric Mean (CV%)	5.73 (70.462)		61.91 (77.062)		7.78 (182.704)	
	95% CI of Geometric Mean	4.96, 6.62		49.76, 77.03		5.19, 11.66	
	Median	5.86	-90.06	65.99	-5.17	7.10	-89.42
	Q25, Q75	4.10, 8.68	-93.22, -87.44	46.92, 108.77	-24.91, 19.61	3.55, 11.09	-93.36, -82.83
	Min, Max	0.9, 27.9	-97.4, -64.6	11.9, 220.5	-68.3, 307.5	1.2, 115.0	-97.8, 0.0
	Mean (SD)	6.97 (4.898)	-89.61 (4.991)	75.49 (45.473)	10.37 (70.590)	17.96 (29.551)	-76.56 (32.044)
	95% CI of Mean	5.85, 8.09	-90.80, -88.42	60.95, 90.04	-13.52, 34.26	8.10, 27.82	-87.41, -65.71

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	20 (26.0)		0		9 (24.3)	
	Geometric Mean (CV%)	3.91 (66.442)		71.54 (59.137)		6.35 (215.188)	
	95% CI of Geometric Mean	3.40, 4.49		60.04, 85.24		4.09, 9.85	
	Median	3.88	-93.58	70.20	3.33	4.50	-92.33
	Q25, Q75	2.65, 5.68	-95.88, -90.49	52.86, 100.02	-13.52, 27.31	2.74, 11.16	-95.74, -85.49
	Min, Max	0.8, 16.3	-97.9, -74.8	19.9, 250.0	-44.5, 167.7	1.1, 115.0	-99.0, 66.5
	Mean (SD)	4.65 (2.915)	-92.49 (4.795)	82.72 (48.090)	15.75 (46.392)	17.67 (30.961)	-74.59 (40.653)
	95% CI of Mean	3.99, 5.32	-93.63, -91.35	67.33, 98.10	0.05, 31.45	7.35, 28.00	-88.35, -60.83

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	27 (35.1)		0		11 (29.7)	
	Geometric Mean (CV%)	3.21 (70.864)		64.64 (55.416)		4.84 (204.793)	
	95% CI of Geometric Mean	2.77, 3.71		54.78, 76.28		3.15, 7.44	
	Median	2.93	-95.17	64.11	0.16	3.45	-94.74
	Q25, Q75	2.07, 4.62	-96.67, -91.92	47.29, 95.36	-25.21, 26.69	2.08, 6.43	-96.04, -88.63
	Min, Max	0.8, 40.0	-99.0, -5.8	22.1, 220.5	-44.1, 114.6	1.1, 115.0	-98.3, 0.0
	Mean (SD)	4.12 (4.688)	-92.83 (11.178)	73.25 (37.963)	8.37 (42.461)	14.98 (30.276)	-80.44 (33.128)
	95% CI of Mean	3.05, 5.19	-95.48, -90.18	61.11, 85.40	-6.00, 22.74	4.88, 25.08	-91.66, -69.23

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	61 (79.2)		0		23 (62.2)	
	Geometric Mean (CV%)	2.53 (62.521)		65.62 (65.054)		3.69 (241.132)	
	95% CI of Geometric Mean	2.22, 2.89		54.26, 79.36		2.32, 5.86	
	Median	2.55	-96.08	71.53	3.78	2.14	-95.69
	Q25, Q75	1.86, 3.44	-97.56, -94.41	46.25, 102.25	-13.17, 19.53	1.46, 4.67	-97.82, -90.78
	Min, Max	0.6, 17.6	-98.7, -62.1	14.7, 220.5	-63.6, 216.0	0.8, 115.0	-99.2, 0.0
	Mean (SD)	3.01 (2.236)	-94.35 (5.749)	76.80 (42.739)	10.13 (51.109)	14.16 (30.572)	-81.46 (33.570)
	95% CI of Mean	2.50, 3.52	-95.72, -92.99	63.13, 90.47	-7.17, 27.42	3.96, 24.36	-92.82, -70.10

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	14 (18.2)		0		5 (13.5)	
	Geometric Mean (CV%)	9.03 (128.250)		65.56 (57.936)		12.69 (193.540)	
	95% CI of Geometric Mean	7.21, 11.29		55.19, 77.87		8.37, 19.25	
	Median	10.18	-83.72	66.71	0.23	15.57	-80.61
	Q25, Q75	4.19, 19.20	-93.40, -66.24	41.35, 105.93	-23.12, 19.97	5.55, 26.23	-87.70, -63.42
	Min, Max	1.0, 88.3	-98.3, 11.1	23.3, 220.5	-59.3, 133.7	0.9, 115.0	-98.3, 0.0
	Mean (SD)	13.96 (14.034)	-77.68 (21.487)	75.38 (41.571)	8.59 (46.207)	24.51 (29.570)	-67.67 (31.978)
	95% CI of Mean	10.76, 17.15	-82.77, -72.59	62.08, 88.68	-7.05, 24.23	14.64, 34.37	-78.49, -56.84

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	12 (15.6)		0		4 (10.8)	
	Geometric Mean (CV%)	9.55 (126.678)		64.52 (70.012)		15.45 (179.869)	
	95% CI of Geometric Mean	7.65, 11.93		52.72, 78.97		10.35, 23.07	
	Median	10.28	-82.89	69.83	1.15	16.46	-78.86
	Q25, Q75	5.16, 21.08	-92.37, -69.45	42.56, 96.09	-16.49, 20.69	9.51, 32.72	-85.67, -54.35
	Min, Max	0.9, 68.0	-98.0, -27.5	10.8, 220.5	-55.6, 141.3	1.1, 115.0	-97.9, 43.7
	Mean (SD)	14.21 (12.260)	-79.18 (16.414)	76.52 (43.403)	9.40 (40.689)	27.58 (29.572)	-61.83 (36.874)
	95% CI of Mean	11.42, 17.00	-83.07, -75.29	62.63, 90.40	-4.37, 23.17	17.71, 37.44	-74.31, -49.35

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	10 (13.0)		0		4 (10.8)	
	Geometric Mean (CV%)	11.19 (127.395)		65.64 (73.905)		17.76 (159.254)	
	95% CI of Geometric Mean	8.95, 13.99		53.14, 81.07		12.20, 25.83	
	Median	13.62	-78.98	77.39	9.42	19.39	-65.48
	Q25, Q75	5.49, 21.11	-89.96, -65.07	45.79, 107.85	-13.83, 27.38	12.90, 27.58	-84.93, -49.85
	Min, Max	1.0, 91.0	-99.4, 54.3	9.1, 220.5	-62.5, 178.2	1.3, 115.0	-98.4, 0.0
	Mean (SD)	16.76 (15.568)	-73.64 (24.226)	78.43 (43.338)	13.82 (50.097)	29.49 (29.852)	-60.36 (29.842)
	95% CI of Mean	13.22, 20.29	-79.38, -67.90	64.56, 92.29	-3.13, 30.78	19.53, 39.45	-70.47, -50.26

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	74	37	37
	Missing, n (%)	6 (7.5)	4 (9.8)	2 (5.1)
	Geometric Mean (CV%)	101.62 (65.623)	108.17 (58.612)	103.33 (67.982)
	95% CI of Geometric Mean	88.46, 116.73	90.24, 129.66	84.13, 126.91
	Median	103.96	112.70	116.51
	Q25, Q75	80.03, 140.42	77.97, 162.59	71.60, 161.07
	Min, Max	15.1, 461.5	25.4, 243.6	15.9, 256.9
	Mean (SD)	119.66 (73.330)	122.61 (57.088)	120.62 (61.814)
	95% CI of Mean	102.66, 136.65	103.57, 141.65	100.01, 141.23

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 1	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	2 (2.6)	0	1 (2.6)
	Geometric Mean (CV%)	20.21 (52.596)	103.12 (59.756)	25.51 (102.925)
	95% CI of Geometric Mean	18.07, 22.60	86.61, 122.77	19.29, 33.74
	Median	20.74	103.91	20.65
	Q25, Q75	15.82, 27.68	73.48, 153.87	15.45, 34.96
	Min, Max	4.4, 91.7	25.1, 307.4	3.7, 256.5
	Mean (SD)	22.68 (11.879)	118.36 (61.762)	40.02 (53.963)
	95% CI of Mean	20.00, 25.36	98.86, 137.86	22.27, 57.76

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 2	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	11 (14.1)	0	4 (10.5)
	Geometric Mean (CV%)	9.52 (62.115)	102.05 (76.031)	12.49 (159.528)
	95% CI of Geometric Mean	8.36, 10.83	82.45, 126.30	8.62, 18.08
	Median	9.94	113.92	9.23
	Q25, Q75	6.94, 13.64	76.41, 154.81	6.25, 17.58
	Min, Max	1.8, 51.1	21.2, 386.2	2.1, 256.5
	Mean (SD)	11.21 (7.597)	123.51 (72.538)	29.56 (56.811)
	95% CI of Mean	9.49, 12.92	100.61, 146.41	10.89, 48.24

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 3	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	20 (25.6)	0	10 (26.3)
	Geometric Mean (CV%)	6.48 (61.915)	116.79 (56.630)	9.80 (204.492)
	95% CI of Geometric Mean	5.69, 7.37	98.87, 137.95	6.42, 14.94
	Median	6.47	126.83	6.81
	Q25, Q75	4.62, 9.66	84.10, 178.27	4.41, 14.13
	Min, Max	1.4, 19.2	19.7, 387.3	1.5, 256.5
	Mean (SD)	7.53 (4.162)	132.07 (66.179)	29.18 (58.678)
	95% CI of Mean	6.59, 8.48	111.18, 152.96	9.89, 48.47

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 4	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	27 (34.6)	0	12 (31.6)
	Geometric Mean (CV%)	5.33 (65.696)	104.93 (55.172)	7.51 (200.465)
	95% CI of Geometric Mean	4.65, 6.10	89.17, 123.48	4.94, 11.41
	Median	5.33	119.78	4.71
	Q25, Q75	3.33, 7.39	68.17, 164.19	3.60, 10.78
	Min, Max	1.6, 63.4	24.5, 250.5	2.2, 256.5
	Mean (SD)	6.68 (7.297)	117.69 (52.705)	25.44 (58.025)
	95% CI of Mean	5.03, 8.33	101.04, 134.33	6.36, 44.52

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 5	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	62 (79.5)	0	24 (63.2)
	Geometric Mean (CV%)	4.31 (56.392)	108.86 (67.185)	6.14 (223.146)
	95% CI of Geometric Mean	3.83, 4.86	89.78, 131.99	3.95, 9.54
	Median	4.38	125.56	4.21
	Q25, Q75	3.16, 5.42	74.13, 170.68	2.64, 7.05
	Min, Max	1.3, 30.8	17.7, 318.9	1.6, 256.5
	Mean (SD)	5.03 (3.715)	127.43 (66.616)	24.38 (58.360)
	95% CI of Mean	4.19, 5.87	106.40, 148.46	5.19, 43.57

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	15 (19.2)	0	5 (13.2)
	Geometric Mean (CV%)	14.47 (137.553)	104.28 (54.224)	20.65 (182.050)
	95% CI of Geometric Mean	11.47, 18.27	88.83, 122.41	13.88, 30.74
	Median	17.36	108.05	23.27
	Q25, Q75	7.24, 31.17	81.56, 145.97	11.01, 40.26
	Min, Max	1.3, 98.4	30.4, 283.1	1.6, 256.5
	Mean (SD)	22.46 (20.791)	117.01 (55.065)	40.22 (55.424)
	95% CI of Mean	17.77, 27.16	99.63, 134.40	21.99, 58.44

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	13 (16.7)	0	4 (10.5)
	Geometric Mean (CV%)	15.15 (124.831)	105.43 (70.037)	25.72 (178.822)
	95% CI of Geometric Mean	12.17, 18.85	86.36, 128.70	17.34, 38.13
	Median	17.34	113.05	25.92
	Q25, Q75	8.27, 31.61	86.98, 153.50	14.12, 67.33
	Min, Max	1.9, 95.0	11.8, 253.8	1.8, 256.5
	Mean (SD)	22.75 (19.954)	122.84 (60.197)	47.20 (56.560)
	95% CI of Mean	18.24, 27.25	103.84, 141.85	28.60, 65.79

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.10.2 Descriptive Statistics of 1-NA in 24-hour Urine Collection - FAS****Parameter (units): 1-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	11 (14.1)	0	4 (10.5)
	Geometric Mean (CV%)	18.42 (121.407)	104.17 (67.670)	28.41 (152.855)
	95% CI of Geometric Mean	14.86, 22.84	85.81, 126.46	19.80, 40.77
	Median	23.76	117.20	27.97
	Q25, Q75	8.21, 35.30	77.80, 163.90	16.80, 50.51
	Min, Max	2.4, 110.3	10.9, 229.4	1.7, 256.5
	Mean (SD)	26.56 (21.349)	120.64 (57.601)	48.00 (56.698)
	95% CI of Mean	21.74, 31.38	102.45, 138.82	29.36, 66.64

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		30		21	
	Missing, n (%)	8 (10.7)		5 (14.3)		3 (12.5)	
	BLOQ, n(%)	2 (3.0)		1 (3.3)		1 (4.8)	
	Geometric Mean (CV%)	17.45 (77.607)		18.65 (67.829)		15.97 (80.918)	
	95% CI of Geometric Mean	14.75, 20.64		14.82, 23.47		11.56, 22.06	
	Median	19.65		19.84		16.04	
	Q25, Q75	14.92, 24.14		13.90, 26.59		12.12, 19.97	
	Min, Max	1.5, 98.8		4.2, 68.3		2.0, 52.1	
	Mean (SD)	20.97 (13.185)		22.25 (14.241)		19.70 (13.129)	
	95% CI of Mean	17.75, 24.19		16.93, 27.57		13.72, 25.68	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	15 (20.5)		0		3 (13.6)	
	Geometric Mean (CV%)	4.54 (69.639)		17.29 (64.758)		4.85 (60.005)	
	95% CI of Geometric Mean	3.91, 5.26		14.06, 21.26		3.79, 6.21	
	Median	4.67	-75.04	17.64	-2.88	4.23	-72.46
	Q25, Q75	3.72, 6.24	-80.11, -70.15	11.31, 24.27	-19.32, 14.33	3.48, 5.61	-75.22, -64.39
	Min, Max	0.7, 42.1	-92.5, 0.0	5.0, 68.3	-49.5, 58.4	2.3, 18.6	-85.5, 41.3
	Mean (SD)	5.58 (5.095)	-71.53 (14.586)	20.52 (13.254)	0.17 (27.995)	5.78 (4.307)	-65.45 (25.931)
	95% CI of Mean	4.39, 6.78	-75.10, -67.97	15.89, 25.15	-10.29, 10.63	3.87, 7.69	-77.26, -53.64

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	35 (47.9)		1 (2.9)		9 (40.9)	
	Geometric Mean (CV%)	2.71 (63.675)		16.14 (89.791)		2.73 (68.110)	
	95% CI of Geometric Mean	2.36, 3.12		12.34, 21.12		2.07, 3.59	
	Median	2.64	-83.71	18.40	-7.28	2.50	-82.40
	Q25, Q75	1.87, 3.86	-90.47, -78.68	11.01, 26.34	-33.14, 26.94	1.77, 3.69	-88.01, -79.48
	Min, Max	0.8, 27.7	-95.8, 17.4	1.6, 68.3	-78.1, 213.8	1.2, 12.0	-93.0, 29.3
	Mean (SD)	3.34 (3.335)	-80.09 (19.099)	20.51 (13.921)	2.90 (56.939)	3.37 (2.722)	-76.86 (26.165)
	95% CI of Mean	2.56, 4.13	-84.75, -75.42	15.65, 25.37	-18.36, 24.17	2.16, 4.58	-88.77, -64.94

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	51 (69.9)		1 (2.9)		10 (45.5)	
	Geometric Mean (CV%)	2.10 (54.223)		18.69 (72.180)		2.68 (83.698)	
	95% CI of Geometric Mean	1.86, 2.37		14.91, 23.43		1.94, 3.71	
	Median	2.08	-89.41	19.57	3.04	2.44	-86.29
	Q25, Q75	1.48, 2.77	-92.04, -84.12	13.62, 26.44	-16.54, 27.81	1.48, 3.74	-90.49, -79.62
	Min, Max	0.7, 9.1	-96.3, 1.3	2.7, 74.1	-47.0, 124.7	1.1, 18.0	-95.8, 74.0
	Mean (SD)	2.40 (1.406)	-84.51 (16.223)	22.58 (15.074)	10.11 (38.597)	3.64 (3.790)	-72.44 (40.534)
	95% CI of Mean	2.06, 2.73	-88.47, -80.54	17.31, 27.84	-4.31, 24.53	1.95, 5.32	-90.90, -53.99

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	48 (65.8)		0		12 (54.5)	
	Geometric Mean (CV%)	2.10 (57.945)		17.31 (62.910)		2.23 (63.975)	
	95% CI of Geometric Mean	1.85, 2.39		14.15, 21.18		1.72, 2.90	
	Median	2.02	-89.62	17.67	-2.50	1.91	-87.08
	Q25, Q75	1.44, 2.72	-92.85, -83.01	13.47, 26.35	-21.93, 28.18	1.37, 3.55	-89.87, -82.48
	Min, Max	0.7, 28.5	-96.9, 150.2	5.2, 68.3	-45.9, 90.0	1.1, 7.2	-94.7, 36.6
	Mean (SD)	2.60 (3.250)	-81.33 (32.570)	20.21 (12.060)	4.15 (36.879)	2.65 (1.679)	-79.57 (28.182)
	95% CI of Mean	1.83, 3.36	-89.28, -73.38	16.00, 24.43	-9.62, 17.93	1.90, 3.40	-92.40, -66.73

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	69 (94.5)		2 (5.9)		16 (72.7)	
	Geometric Mean (CV%)	2.10 (57.112)		16.28 (69.274)		1.98 (65.041)	
	95% CI of Geometric Mean	1.85, 2.39		13.08, 20.26		1.52, 2.58	
	Median	2.09	-88.98	16.50	-8.18	2.06	-89.84
	Q25, Q75	1.39, 3.27	-93.20, -81.45	11.08, 25.94	-26.16, 16.71	1.26, 2.74	-91.70, -84.81
	Min, Max	0.6, 6.8	-96.7, 53.9	3.0, 68.3	-69.3, 166.0	0.8, 10.2	-96.9, 4.2
	Mean (SD)	2.42 (1.358)	-80.97 (26.848)	19.39 (12.104)	0.23 (44.877)	2.41 (1.997)	-82.14 (22.171)
	95% CI of Mean	2.10, 2.74	-87.52, -74.41	15.16, 23.62	-16.54, 16.99	1.52, 3.30	-92.23, -72.04

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		29		12	
	Missing, n (%)	3 (7.5)		5 (14.7)		1 (7.7)	
	BLOQ, n(%)	0		1 (3.4)		0	
	Geometric Mean (CV%)	17.71 (72.691)		17.21 (65.090)		18.29 (55.763)	
	95% CI of Geometric Mean	14.25, 22.01		13.72, 21.58		13.14, 25.46	
	Median	20.06		17.39		15.89	
	Q25, Q75	14.11, 23.96		13.49, 24.36		13.15, 26.89	
	Min, Max	1.5, 98.8		4.2, 54.1		9.6, 52.1	
	Mean (SD)	21.31 (15.410)		20.18 (11.722)		20.99 (12.874)	
	95% CI of Mean	16.17, 26.46		15.72, 24.65		12.80, 29.17	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	37	33	29	13	12
	Missing, n (%)	0	3 (7.5)	1 (2.9)	5 (14.7)	0	1 (7.7)
	BLOQ, n(%)	21 (52.5)		1 (3.0)		6 (46.2)	
	Geometric Mean (CV%)	3.13 (86.075)		16.89 (62.583)		3.51 (105.581)	
	95% CI of Geometric Mean	2.46, 3.97		13.77, 20.71		2.08, 5.93	
	Median	3.12	-82.58	16.60	6.58	3.59	-81.82
	Q25, Q75	1.71, 4.72	-91.41, -67.33	11.11, 26.33	-26.17, 29.24	2.22, 5.63	-90.40, -74.06
	Min, Max	0.8, 12.3	-98.6, -15.9	3.4, 41.0	-53.4, 141.2	1.0, 16.1	-93.7, 55.0
	Mean (SD)	4.11 (3.223)	-75.87 (21.560)	19.50 (10.073)	9.76 (46.553)	4.99 (4.639)	-70.84 (40.732)
	95% CI of Mean	3.07, 5.14	-83.07, -68.68	15.92, 23.08	-7.95, 27.48	2.18, 7.79	-96.72, -44.95

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	35		30		11	
	Missing, n (%)	4 (10.3)		5 (14.3)		1 (8.3)	
	BLOQ, n(%)	1 (2.9)		1 (3.3)		1 (9.1)	
	Geometric Mean (CV%)	17.57 (90.733)		17.33 (63.934)		13.49 (88.049)	
	95% CI of Geometric Mean	13.45, 22.93		13.93, 21.57		8.11, 22.45	
	Median	20.11		18.35		15.68	
	Q25, Q75	15.09, 27.18		13.49, 24.36		10.41, 16.40	
	Min, Max	1.5, 98.8		4.2, 54.1		2.0, 35.8	
	Mean (SD)	21.93 (15.766)		20.23 (11.521)		16.52 (9.960)	
	95% CI of Mean	16.51, 27.35		15.92, 24.53		9.83, 23.22	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	35	34	30	11	11
	Missing, n (%)	0	4 (10.3)	1 (2.9)	5 (14.3)	1 (8.3)	1 (8.3)
	BLOQ, n(%)	23 (59.0)		1 (2.9)		5 (45.5)	
	Geometric Mean (CV%)	3.01 (82.128)		15.94 (77.238)		3.50 (120.096)	
	95% CI of Geometric Mean	2.38, 3.81		12.55, 20.24		1.85, 6.60	
	Median	3.01	-82.29	19.23	-2.14	2.71	-75.37
	Q25, Q75	1.70, 4.84	-91.21, -73.72	10.45, 24.07	-16.03, 25.46	1.79, 5.49	-89.11, -55.10
	Min, Max	0.8, 14.1	-98.2, 119.2	2.3, 47.9	-50.7, 77.3	1.2, 20.3	-92.0, 95.0
	Mean (SD)	3.91 (3.185)	-75.39 (36.443)	19.40 (11.477)	3.87 (33.411)	5.56 (6.450)	-58.97 (53.353)
	95% CI of Mean	2.87, 4.95	-87.91, -62.86	15.39, 23.40	-8.61, 16.35	1.23, 9.90	-94.82, -23.12

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	43		29		9	
	Missing, n (%)	4 (8.5)		3 (9.4)		0	
	BLOQ, n(%)	1 (2.3)		1 (3.4)		1 (11.1)	
	Geometric Mean (CV%)	18.16 (84.255)		17.23 (65.152)		11.90 (88.448)	
	95% CI of Geometric Mean	14.49, 22.76		13.74, 21.61		6.63, 21.36	
	Median	20.11		17.39		14.17	
	Q25, Q75	15.07, 27.35		13.49, 24.36		10.41, 16.04	
	Min, Max	1.5, 98.8		4.2, 54.1		2.0, 33.8	
	Mean (SD)	22.23 (14.962)		20.21 (11.724)		14.47 (8.536)	
	95% CI of Mean	17.62, 26.84		15.75, 24.67		7.90, 21.03	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	43	32	29	9	9
	Missing, n (%)	0	4 (8.5)	0	3 (9.4)	0	
	BLOQ, n(%)	27 (57.4)		1 (3.1)		5 (55.6)	
	Geometric Mean (CV%)	3.21 (87.182)		17.29 (73.960)		3.03 (76.436)	
	95% CI of Geometric Mean	2.57, 4.00		13.62, 21.95		1.80, 5.11	
	Median	2.86	-83.43	17.75	2.40	3.26	-71.12
	Q25, Q75	1.73, 5.58	-91.08, -67.50	12.58, 27.83	-20.11, 31.36	1.51, 4.20	-90.34, -66.42
	Min, Max	1.0, 19.8	-98.7, 18.2	2.9, 53.2	-50.5, 145.2	1.3, 10.5	-91.0, 0.9
	Mean (SD)	4.34 (3.949)	-77.01 (21.508)	20.80 (12.141)	11.04 (44.201)	3.76 (2.862)	-64.26 (31.765)
	95% CI of Mean	3.17, 5.50	-83.63, -70.39	16.41, 25.18	-5.78, 27.86	1.55, 5.96	-88.69, -39.84

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	70	31	22
	Missing, n (%)	5 (6.7)	4 (11.4)	2 (8.3)
	BLOQ, n(%)	2 (2.9)	1 (3.2)	1 (4.5)
	Geometric Mean (CV%)	28.80 (75.807)	30.25 (66.063)	25.76 (76.777)
	95% CI of Geometric Mean	24.52, 33.82	24.25, 37.72	19.04, 34.84
	Median	33.01	32.85	25.61
	Q25, Q75	21.41, 42.80	24.84, 42.06	22.46, 39.29
	Min, Max	3.0, 111.3	4.8, 67.1	3.0, 61.7
	Mean (SD)	34.65 (20.252)	34.91 (16.765)	30.58 (16.312)
	95% CI of Mean	29.82, 39.48	28.76, 41.07	23.35, 37.82

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	15 (20.3)	0	3 (13.0)
	Geometric Mean (CV%)	7.48 (57.801)	28.59 (60.716)	7.73 (54.053)
	95% CI of Geometric Mean	6.60, 8.48	23.58, 34.67	6.21, 9.63
	Median	8.47	30.91	7.56
	Q25, Q75	5.71, 10.48	20.94, 43.56	5.75, 10.27
	Min, Max	1.6, 24.9	7.8, 82.4	3.3, 19.2
	Mean (SD)	8.51 (4.226)	32.95 (17.590)	8.77 (4.755)
	95% CI of Mean	7.52, 9.49	26.90, 39.00	6.71, 10.83

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	35 (47.3)	1 (2.9)	10 (43.5)
	Geometric Mean (CV%)	4.53 (58.929)	26.81 (87.337)	4.35 (52.081)
	95% CI of Geometric Mean	3.99, 5.15	20.69, 34.73	3.52, 5.38
	Median	4.68	29.79	3.78
	Q25, Q75	3.06, 6.28	21.54, 42.54	2.95, 5.98
	Min, Max	1.8, 50.7	2.8, 117.2	2.1, 12.7
	Mean (SD)	5.50 (5.803)	33.56 (21.659)	4.92 (2.753)
	95% CI of Mean	4.15, 6.85	26.12, 41.01	3.73, 6.12

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	52 (70.3)	1 (2.9)	11 (47.8)
	Geometric Mean (CV%)	3.47 (51.577)	30.83 (68.558)	4.09 (69.647)
	95% CI of Geometric Mean	3.10, 3.89	24.91, 38.16	3.11, 5.38
	Median	3.39	32.57	3.54
	Q25, Q75	2.26, 4.72	21.67, 47.72	2.66, 6.26
	Min, Max	1.4, 11.1	5.1, 114.8	1.9, 27.6
	Mean (SD)	3.92 (2.137)	36.06 (19.888)	5.24 (5.352)
	95% CI of Mean	3.42, 4.42	29.23, 42.90	2.92, 7.56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	49 (66.2)	0	13 (56.5)
	Geometric Mean (CV%)	3.49 (54.621)	28.11 (61.699)	3.44 (49.901)
	95% CI of Geometric Mean	3.10, 3.94	23.13, 34.18	2.80, 4.22
	Median	3.24	30.86	3.45
	Q25, Q75	2.52, 4.57	18.46, 43.57	2.39, 4.25
	Min, Max	1.0, 45.1	5.7, 66.8	1.7, 12.6
	Mean (SD)	4.23 (5.059)	32.21 (15.618)	3.89 (2.409)
	95% CI of Mean	3.05, 5.41	26.84, 37.58	2.84, 4.94

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	70 (94.6)	2 (5.7)	17 (73.9)
	Geometric Mean (CV%)	3.60 (48.759)	27.07 (72.875)	3.29 (51.309)
	95% CI of Geometric Mean	3.23, 4.01	21.63, 33.88	2.67, 4.06
	Median	3.45	32.12	3.11
	Q25, Q75	2.51, 4.90	18.46, 39.06	2.56, 3.74
	Min, Max	1.3, 11.1	3.7, 73.6	1.6, 11.7
	Mean (SD)	4.01 (2.023)	32.07 (16.907)	3.74 (2.280)
	95% CI of Mean	3.54, 4.49	26.26, 37.89	2.75, 4.73

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set**

Parameter (units): 2-NA (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	38	30	12
	Missing, n (%)	2 (5.0)	4 (11.8)	1 (7.7)
	BLOQ, n(%)	0	1 (3.3)	0
	Geometric Mean (CV%)	28.75 (67.544)	28.92 (68.165)	28.65 (44.004)
	95% CI of Geometric Mean	23.50, 35.17	22.96, 36.43	21.93, 37.44
	Median	29.37	31.53	24.55
	Q25, Q75	21.24, 45.75	23.31, 42.03	21.79, 37.83
	Min, Max	3.8, 111.3	4.8, 67.1	15.5, 61.1
	Mean (SD)	33.78 (19.520)	33.74 (17.018)	31.24 (14.531)
	95% CI of Mean	27.36, 40.20	27.38, 40.10	22.00, 40.47

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (ng)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Day 30	n	40	34	13
	BLOQ, n(%)	21 (52.5)	1 (2.9)	6 (46.2)
	Geometric Mean (CV%)	5.07 (88.258)	28.46 (56.728)	5.77 (109.779)
	95% CI of Geometric Mean	3.97, 6.46	23.67, 34.23	3.37, 9.88
	Median	4.59	29.58	5.74
	Q25, Q75	2.43, 9.28	21.61, 40.09	2.77, 11.72
	Min, Max	1.8, 29.3	6.6, 79.4	1.6, 31.1
	Mean (SD)	6.80 (5.861)	32.19 (15.874)	8.31 (7.992)
	95% CI of Mean	4.92, 8.68	26.64, 37.73	3.47, 13.14

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set**

Parameter (units): 2-NA (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	37	31	12
	Missing, n (%)	2 (5.1)	4 (11.4)	0
	BLOQ, n(%)	1 (2.7)	1 (3.2)	1 (8.3)
	Geometric Mean (CV%)	28.17 (88.368)	28.92 (66.793)	22.38 (83.841)
	95% CI of Geometric Mean	21.86, 36.30	23.14, 36.15	14.07, 35.58
	Median	33.16	30.22	23.93
	Q25, Q75	21.24, 47.57	23.31, 42.03	20.39, 32.26
	Min, Max	3.0, 111.3	4.8, 67.1	3.0, 61.1
	Mean (SD)	35.05 (21.193)	33.58 (16.754)	26.71 (14.304)
	95% CI of Mean	27.97, 42.12	27.43, 39.73	17.62, 35.81

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (ng)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Day 60	n	39	35	12
	BLOQ, n(%)	23 (59.0)	1 (2.9)	6 (50.0)
	Geometric Mean (CV%)	4.89 (81.996)	26.99 (76.836)	5.49 (125.741)
	95% CI of Geometric Mean	3.87, 6.18	21.35, 34.11	2.95, 10.20
	Median	3.82	29.87	5.45
	Q25, Q75	2.95, 6.58	19.84, 46.37	2.47, 8.43
	Min, Max	1.9, 34.2	2.6, 66.7	1.8, 32.6
	Mean (SD)	6.66 (6.810)	32.18 (16.769)	8.95 (10.543)
	95% CI of Mean	4.44, 8.87	26.41, 37.94	2.25, 15.66

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (ng)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	45	29	9
	Missing, n (%)	2 (4.3)	3 (9.4)	0
	BLOQ, n(%)	1 (2.2)	1 (3.4)	1 (11.1)
	Geometric Mean (CV%)	28.86 (83.531)	28.19 (67.556)	19.30 (87.879)
	95% CI of Geometric Mean	23.19, 35.92	22.32, 35.60	10.79, 34.53
	Median	33.16	30.22	22.56
	Q25, Q75	21.24, 47.12	23.31, 40.60	19.76, 25.04
	Min, Max	3.0, 111.3	4.8, 67.1	3.0, 40.3
	Mean (SD)	35.58 (21.898)	32.82 (16.602)	22.95 (10.776)
	95% CI of Mean	29.00, 42.16	26.50, 39.14	14.66, 31.24

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.1 Descriptive Statistics of 2-NA in 24-hour Urine Collection - PP Set****Parameter (units): 2-NA (ng)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Day 90	n	47	32	9
	BLOQ, n(%)	27 (57.4)	1 (3.1)	5 (55.6)
	Geometric Mean (CV%)	5.38 (91.101)	28.71 (72.281)	5.19 (96.509)
	95% CI of Geometric Mean	4.28, 6.76	22.72, 36.28	2.78, 9.69
	Median	3.96	31.77	6.57
	Q25, Q75	3.00, 9.11	18.83, 44.92	3.17, 7.56
	Min, Max	1.6, 27.0	3.5, 68.5	1.7, 21.5
	Mean (SD)	7.44 (6.870)	33.95 (17.819)	6.97 (6.092)
	95% CI of Mean	5.42, 9.46	27.52, 40.38	2.28, 11.66

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		36		36	
	Missing, n (%)	9 (11.3)		5 (12.2)		3 (7.7)	
	BLOQ, n(%)	2 (2.8)		1 (2.8)		1 (2.8)	
	Geometric Mean (CV%)	17.57 (75.518)		19.56 (68.121)		18.02 (71.979)	
	95% CI of Geometric Mean	14.98, 20.60		15.87, 24.11		14.48, 22.43	
	Median	19.56		21.08		17.23	
	Q25, Q75	15.07, 24.14		14.78, 28.34		13.16, 26.97	
	Min, Max	1.5, 98.8		4.2, 68.3		2.0, 52.1	
	Mean (SD)	20.96 (12.931)		23.24 (14.013)		21.43 (12.201)	
	95% CI of Mean	17.90, 24.03		18.50, 27.99		17.30, 25.57	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	15 (19.5)		0		4 (10.8)	
	Geometric Mean (CV%)	4.56 (68.582)		18.08 (62.802)		5.89 (88.720)	
	95% CI of Geometric Mean	3.95, 5.25		15.03, 21.75		4.57, 7.60	
	Median	4.58	-75.07	18.74	-3.12	5.27	-72.37
	Q25, Q75	3.72, 6.24	-79.34, -70.15	11.68, 26.77	-18.41, 13.65	3.50, 8.14	-77.81, -60.84
	Min, Max	0.7, 42.1	-92.5, 0.0	5.0, 68.3	-49.5, 58.4	1.1, 37.6	-89.0, 41.3
	Mean (SD)	5.58 (5.004)	-71.71 (14.207)	21.18 (12.682)	-0.50 (26.988)	8.10 (7.809)	-59.52 (31.736)
	95% CI of Mean	4.44, 6.72	-75.07, -68.34	17.12, 25.25	-9.64, 8.63	5.49, 10.71	-70.26, -48.77

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	36 (46.8)		1 (2.5)		14 (37.8)	
	Geometric Mean (CV%)	2.73 (62.814)		17.24 (85.823)		3.48 (123.887)	
	95% CI of Geometric Mean	2.39, 3.12		13.59, 21.87		2.52, 4.81	
	Median	2.64	-83.85	19.31	-6.95	2.89	-82.88
	Q25, Q75	1.92, 3.86	-89.89, -79.24	13.04, 27.78	-31.73, 19.70	1.77, 4.73	-88.56, -75.29
	Min, Max	0.8, 27.7	-95.8, 17.4	1.6, 68.3	-78.1, 213.8	0.6, 37.6	-95.7, 29.3
	Mean (SD)	3.34 (3.268)	-80.34 (18.579)	21.50 (13.670)	2.99 (52.862)	5.99 (8.036)	-69.18 (34.845)
	95% CI of Mean	2.60, 4.09	-84.74, -75.94	17.13, 25.88	-14.90, 20.88	3.30, 8.67	-80.98, -57.39

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	54 (70.1)		1 (2.5)		17 (45.9)	
	Geometric Mean (CV%)	2.08 (55.490)		19.49 (72.158)		3.31 (130.683)	
	95% CI of Geometric Mean	1.84, 2.34		15.84, 23.98		2.37, 4.63	
	Median	2.05	-89.64	20.80	3.04	2.64	-86.30
	Q25, Q75	1.48, 2.77	-92.04, -84.12	13.87, 28.65	-12.03, 18.20	1.60, 4.44	-90.67, -70.86
	Min, Max	0.7, 9.1	-96.3, 1.3	2.7, 74.1	-47.0, 124.7	1.1, 37.6	-97.5, 74.0
	Mean (SD)	2.39 (1.431)	-84.83 (15.839)	23.41 (14.646)	8.39 (35.452)	5.99 (8.279)	-66.98 (41.744)
	95% CI of Mean	2.06, 2.72	-88.59, -81.08	18.72, 28.10	-3.61, 20.39	3.23, 8.76	-81.11, -52.85

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	51 (66.2)		0		18 (48.6)	
	Geometric Mean (CV%)	2.08 (57.143)		18.45 (61.696)		2.97 (122.971)	
	95% CI of Geometric Mean	1.84, 2.36		15.38, 22.13		2.15, 4.09	
	Median	2.02	-89.70	19.68	-2.50	2.74	-87.32
	Q25, Q75	1.42, 2.72	-92.63, -84.10	13.61, 28.03	-20.82, 25.95	1.52, 3.75	-90.59, -79.74
	Min, Max	0.7, 28.5	-96.9, 150.2	5.2, 68.3	-45.9, 90.0	1.1, 37.6	-94.7, 36.6
	Mean (SD)	2.56 (3.171)	-81.86 (31.703)	21.35 (11.832)	5.18 (36.135)	5.37 (8.059)	-71.23 (36.370)
	95% CI of Mean	1.84, 3.29	-89.37, -74.35	17.56, 25.14	-7.05, 17.41	2.68, 8.06	-83.54, -58.92

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	72 (93.5)		3 (7.5)		25 (67.6)	
	Geometric Mean (CV%)	2.13 (55.972)		16.96 (79.964)		2.74 (126.785)	
	95% CI of Geometric Mean	1.89, 2.40		13.54, 21.25		1.97, 3.80	
	Median	2.10	-88.98	17.93	-3.43	2.12	-89.71
	Q25, Q75	1.41, 3.27	-93.19, -81.45	11.20, 27.05	-24.38, 12.31	1.41, 2.98	-91.90, -72.77
	Min, Max	0.6, 6.8	-96.7, 53.9	2.4, 68.3	-69.3, 166.0	0.8, 37.6	-96.9, 4.2
	Mean (SD)	2.44 (1.330)	-81.23 (26.118)	20.81 (12.956)	-0.96 (42.523)	5.20 (8.158)	-72.59 (34.337)
	95% CI of Mean	2.13, 2.74	-87.42, -75.04	16.66, 24.96	-15.35, 13.43	2.48, 7.93	-84.21, -60.97

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	33 (42.9)		1 (2.5)		12 (32.4)	
	Geometric Mean (CV%)	3.59 (82.985)		18.32 (64.992)		5.10 (131.574)	
	95% CI of Geometric Mean	3.04, 4.23		15.15, 22.16		3.64, 7.13	
	Median	3.53	-80.71	18.78	1.49	5.28	-75.15
	Q25, Q75	2.17, 6.60	-90.35, -61.96	11.32, 28.69	-26.88, 21.73	2.30, 7.61	-85.17, -45.25
	Min, Max	0.8, 25.4	-98.6, 49.0	3.4, 68.3	-53.4, 141.2	0.9, 37.6	-93.7, 55.0
	Mean (SD)	4.67 (3.832)	-72.07 (26.362)	21.49 (12.439)	4.54 (43.727)	8.17 (8.632)	-58.84 (37.263)
	95% CI of Mean	3.79, 5.54	-78.31, -65.82	17.51, 25.47	-10.26, 19.34	5.29, 11.06	-71.45, -46.22

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	33 (42.9)		1 (2.5)		7 (18.9)	
	Geometric Mean (CV%)	3.75 (90.620)		17.64 (78.497)		5.97 (115.118)	
	95% CI of Geometric Mean	3.14, 4.48		14.13, 22.02		4.39, 8.11	
	Median	3.93	-79.48	20.93	-2.60	6.15	-72.65
	Q25, Q75	1.97, 6.34	-89.91, -57.76	10.75, 27.94	-16.65, 16.99	2.95, 9.40	-80.02, -47.29
	Min, Max	0.8, 21.8	-98.2, 119.2	2.3, 68.3	-50.7, 77.3	1.1, 37.6	-92.0, 95.0
	Mean (SD)	4.99 (3.934)	-70.74 (30.136)	21.62 (13.430)	1.41 (31.687)	8.85 (8.352)	-55.67 (39.434)
	95% CI of Mean	4.09, 5.88	-77.88, -63.60	17.32, 25.92	-9.32, 12.13	6.06, 11.64	-69.02, -42.33

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	36 (46.8)		1 (2.5)		7 (18.9)	
	Geometric Mean (CV%)	3.79 (92.563)		18.80 (77.350)		6.29 (107.142)	
	95% CI of Geometric Mean	3.16, 4.53		15.10, 23.41		4.69, 8.42	
	Median	3.63	-80.58	21.83	1.20	6.91	-63.74
	Q25, Q75	1.94, 6.92	-88.89, -61.44	12.60, 31.26	-17.26, 19.66	3.56, 10.51	-79.30, -44.14
	Min, Max	1.0, 21.3	-98.7, 18.2	2.9, 68.3	-50.5, 145.2	1.3, 37.6	-92.9, 0.9
	Mean (SD)	5.13 (4.255)	-71.93 (22.570)	22.91 (13.822)	9.01 (40.213)	9.04 (8.274)	-55.62 (30.158)
	95% CI of Mean	4.16, 6.10	-77.28, -66.58	18.48, 27.33	-4.60, 22.62	6.27, 11.80	-65.83, -45.41

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	74	37	37
	Missing, n (%)	6 (7.5)	4 (9.8)	2 (5.1)
	BLOQ, n(%)	2 (2.7)	1 (2.7)	1 (2.7)
	Geometric Mean (CV%)	29.03 (73.726)	31.81 (65.979)	29.48 (69.656)
	95% CI of Geometric Mean	24.92, 33.82	26.03, 38.88	23.90, 36.36
	Median	33.01	35.36	27.96
	Q25, Q75	21.68, 42.80	25.40, 53.28	22.56, 45.93
	Min, Max	3.0, 111.3	4.8, 67.1	3.0, 83.9
	Mean (SD)	34.64 (19.789)	36.71 (17.296)	34.60 (18.797)
	95% CI of Mean	30.05, 39.23	30.94, 42.48	28.33, 40.87

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 1	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	15 (19.2)	0	4 (10.5)
	Geometric Mean (CV%)	7.50 (56.593)	29.73 (58.354)	9.67 (82.156)
	95% CI of Geometric Mean	6.65, 8.45	25.06, 35.28	7.63, 12.25
	Median	8.37	31.08	8.47
	Q25, Q75	5.71, 10.48	21.66, 46.37	6.08, 13.82
	Min, Max	1.6, 24.9	7.8, 82.4	3.3, 83.9
	Mean (SD)	8.49 (4.156)	33.90 (17.085)	13.23 (14.754)
	95% CI of Mean	7.55, 9.43	28.50, 39.30	8.38, 18.09

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 2	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	36 (46.2)	1 (2.4)	15 (39.5)
	Geometric Mean (CV%)	4.54 (57.597)	28.48 (82.287)	5.66 (111.765)
	95% CI of Geometric Mean	4.02, 5.13	22.69, 35.74	4.20, 7.61
	Median	4.71	31.91	4.65
	Q25, Q75	3.09, 6.28	23.80, 48.39	2.99, 8.40
	Min, Max	1.8, 50.7	2.8, 117.2	1.6, 83.9
	Mean (SD)	5.47 (5.660)	34.83 (20.689)	9.79 (15.518)
	95% CI of Mean	4.19, 6.75	28.30, 41.37	4.69, 14.90

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 3	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	55 (70.5)	1 (2.4)	18 (47.4)
	Geometric Mean (CV%)	3.43 (52.069)	31.87 (66.799)	5.20 (125.802)
	95% CI of Geometric Mean	3.07, 3.84	26.31, 38.62	3.77, 7.17
	Median	3.30	32.86	3.95
	Q25, Q75	2.24, 4.72	25.59, 47.72	2.67, 7.62
	Min, Max	1.4, 11.1	5.1, 114.8	1.5, 83.9
	Mean (SD)	3.89 (2.130)	37.02 (19.445)	9.76 (15.914)
	95% CI of Mean	3.40, 4.37	30.87, 43.16	4.53, 15.00

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 4	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	52 (66.7)	0	19 (50.0)
	Geometric Mean (CV%)	3.45 (53.994)	30.02 (60.028)	4.66 (119.257)
	95% CI of Geometric Mean	3.07, 3.87	25.20, 35.77	3.41, 6.35
	Median	3.24	32.29	3.67
	Q25, Q75	2.52, 4.46	22.83, 46.91	2.43, 4.68
	Min, Max	1.0, 45.1	5.7, 66.8	1.7, 83.9
	Mean (SD)	4.16 (4.938)	34.10 (15.549)	8.89 (15.748)
	95% CI of Mean	3.04, 5.28	29.19, 39.01	3.71, 14.07

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 5	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	73 (93.6)	3 (7.3)	26 (68.4)
	Geometric Mean (CV%)	3.64 (48.451)	28.28 (80.832)	4.60 (120.375)
	95% CI of Geometric Mean	3.28, 4.04	22.60, 35.37	3.37, 6.28
	Median	3.45	36.00	3.33
	Q25, Q75	2.60, 4.90	18.54, 50.41	2.56, 5.21
	Min, Max	1.3, 11.1	3.7, 73.6	1.6, 83.9
	Mean (SD)	4.05 (2.024)	34.25 (18.137)	8.84 (15.750)
	95% CI of Mean	3.59, 4.51	28.52, 39.98	3.65, 14.02

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	34 (43.6)	1 (2.4)	13 (34.2)
	Geometric Mean (CV%)	5.82 (82.876)	29.27 (58.993)	8.15 (132.941)
	95% CI of Geometric Mean	4.94, 6.86	24.63, 34.78	5.85, 11.36
	Median	5.92	30.07	8.68
	Q25, Q75	3.21, 10.49	22.61, 42.66	3.44, 14.24
	Min, Max	1.3, 29.3	6.6, 79.4	1.6, 83.9
	Mean (SD)	7.52 (5.727)	33.28 (16.100)	13.42 (15.832)
	95% CI of Mean	6.22, 8.81	28.19, 38.36	8.21, 18.63

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	34 (43.6)	1 (2.4)	8 (21.1)
	Geometric Mean (CV%)	6.02 (92.435)	28.96 (73.631)	9.77 (124.823)
	95% CI of Geometric Mean	5.04, 7.19	23.52, 35.65	7.10, 13.44
	Median	5.67	34.62	9.75
	Q25, Q75	3.17, 10.48	21.38, 47.25	5.09, 19.52
	Min, Max	1.0, 34.2	2.6, 66.7	1.8, 83.9
	Mean (SD)	8.16 (6.840)	34.05 (16.629)	15.28 (16.398)
	95% CI of Mean	6.62, 9.71	28.80, 39.30	9.88, 20.67

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.11.2 Descriptive Statistics of 2-NA in 24-hour Urine Collection - FAS****Parameter (units): 2-NA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	37 (47.4)	1 (2.4)	8 (21.1)
	Geometric Mean (CV%)	6.32 (92.635)	29.95 (69.827)	9.92 (111.373)
	95% CI of Geometric Mean	5.29, 7.55	24.54, 36.54	7.38, 13.33
	Median	6.02	36.15	9.50
	Q25, Q75	3.36, 12.51	19.13, 45.67	6.57, 16.43
	Min, Max	1.6, 27.0	3.5, 68.5	1.7, 83.9
	Mean (SD)	8.57 (6.928)	35.00 (17.150)	14.72 (15.625)
	95% CI of Mean	7.00, 10.14	29.58, 40.42	9.58, 19.86

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		30		21	
	Missing, n (%)	8 (10.7)		5 (14.3)		3 (12.5)	
	BLOQ, n(%)	18 (26.9)		5 (16.7)		5 (23.8)	
	Geometric Mean (CV%)	98.12 (65.839)		114.59 (62.576)		94.65 (60.257)	
	95% CI of Geometric Mean	84.75, 113.59		92.45, 142.04		73.46, 121.95	
	Median	107.96		118.98		92.57	
	Q25, Q75	67.09, 147.21		80.68, 168.03		62.50, 146.60	
	Min, Max	12.4, 685.4		26.3, 299.3		38.4, 267.2	
	Mean (SD)	116.79 (85.681)		132.47 (70.085)		109.35 (60.316)	
	95% CI of Mean	95.88, 137.69		106.30, 158.65		81.89, 136.81	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	50 (68.5)		6 (17.6)		10 (45.5)	
	Geometric Mean (CV%)	43.11 (53.069)		103.88 (61.390)		44.28 (65.397)	
	95% CI of Geometric Mean	38.37, 48.42		85.27, 126.54		33.98, 57.70	
	Median	39.75	-58.77	107.70	-14.58	42.19	-62.74
	Q25, Q75	30.56, 58.82	-73.09, -28.89	60.20, 153.74	-30.16, 6.36	27.96, 65.16	-69.80, -45.41
	Min, Max	14.0, 206.9	-86.2, 99.0	31.8, 312.5	-45.1, 140.3	18.9, 142.9	-86.0, 272.0
	Mean (SD)	49.12 (29.224)	-47.54 (34.881)	120.93 (69.010)	-0.64 (42.945)	53.08 (35.611)	-37.92 (76.651)
	95% CI of Mean	42.30, 55.95	-56.05, -39.02	96.84, 145.01	-16.68, 15.40	37.29, 68.87	-72.82, -3.03

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	59 (80.8)		11 (32.4)		16 (72.7)	
	Geometric Mean (CV%)	37.27 (48.034)		91.90 (75.586)		34.75 (48.417)	
	95% CI of Geometric Mean	33.51, 41.46		72.68, 116.20		28.35, 42.59	
	Median	36.98	-65.54	105.37	-8.95	34.24	-69.00
	Q25, Q75	27.17, 47.73	-76.61, -34.30	56.82, 160.89	-40.21, 9.50	23.15, 48.90	-74.99, -57.63
	Min, Max	15.3, 152.8	-88.6, 58.0	17.9, 277.0	-77.6, 196.3	15.9, 85.5	-85.3, 121.7
	Mean (SD)	41.79 (24.078)	-52.12 (33.515)	111.67 (66.761)	-2.36 (59.498)	38.51 (18.869)	-51.39 (48.336)
	95% CI of Mean	36.16, 47.41	-60.30, -43.94	88.37, 134.97	-24.58, 19.86	30.14, 46.88	-73.40, -29.39

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	50 (68.5)		6 (17.6)		13 (59.1)	
	Geometric Mean (CV%)	42.02 (40.527)		116.74 (62.078)		40.50 (61.407)	
	95% CI of Geometric Mean	38.36, 46.02		95.65, 142.48		31.51, 52.04	
	Median	43.43	-58.02	122.75	-2.23	40.03	-63.59
	Q25, Q75	32.38, 54.82	-73.42, -31.83	78.95, 168.78	-26.91, 17.99	25.56, 61.85	-73.78, -48.47
	Min, Max	16.7, 102.2	-90.0, 34.0	28.9, 428.6	-48.9, 287.5	11.3, 107.1	-82.8, 74.0
	Mean (SD)	45.23 (17.728)	-48.69 (31.911)	136.22 (80.457)	14.22 (71.030)	46.81 (25.448)	-49.15 (40.016)
	95% CI of Mean	41.09, 49.37	-56.48, -40.91	108.14, 164.30	-12.31, 40.75	35.52, 58.10	-67.37, -30.93

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	53 (72.6)		5 (14.7)		16 (72.7)	
	Geometric Mean (CV%)	37.82 (41.831)		103.85 (52.438)		36.36 (62.593)	
	95% CI of Geometric Mean	34.43, 41.54		87.43, 123.34		28.17, 46.92	
	Median	37.83	-64.13	101.58	-2.25	36.02	-72.36
	Q25, Q75	28.44, 48.52	-77.39, -41.75	78.81, 147.09	-25.88, 14.36	23.15, 59.45	-78.03, -34.96
	Min, Max	16.3, 122.2	-88.1, 140.4	38.2, 277.0	-55.3, 216.1	10.2, 96.2	-88.8, 53.8
	Mean (SD)	41.09 (18.421)	-51.57 (38.687)	116.43 (56.927)	3.22 (51.480)	42.13 (22.623)	-49.99 (42.198)
	95% CI of Mean	36.79, 45.39	-61.01, -42.12	96.56, 136.29	-16.01, 22.45	32.09, 52.16	-69.20, -30.77

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	68 (93.2)		13 (38.2)		19 (86.4)	
	Geometric Mean (CV%)	42.20 (50.008)		92.68 (53.429)		34.05 (60.843)	
	95% CI of Geometric Mean	37.79, 47.13		77.80, 110.39		26.55, 43.68	
	Median	40.19	-61.51	81.81	-13.66	37.95	-68.05
	Q25, Q75	29.34, 58.41	-76.99, -17.28	61.58, 142.83	-32.85, 4.05	23.15, 46.84	-78.66, -58.15
	Min, Max	12.4, 136.6	-91.9, 261.2	39.0, 277.0	-76.8, 88.7	9.3, 101.9	-87.2, 46.0
	Mean (SD)	47.29 (24.441)	-40.73 (55.552)	105.12 (56.627)	-10.68 (37.630)	39.46 (22.888)	-54.59 (36.919)
	95% CI of Mean	41.58, 52.99	-54.28, -27.17	85.35, 124.88	-24.74, 3.37	29.31, 49.62	-71.40, -37.78

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		29		12	
	Missing, n (%)	3 (7.5)		5 (14.7)		1 (7.7)	
	BLOQ, n(%)	12 (32.4)		5 (17.2)		2 (16.7)	
	Geometric Mean (CV%)	91.82 (75.995)		108.37 (60.677)		100.78 (51.904)	
	95% CI of Geometric Mean	73.31, 115.01		87.58, 134.10		73.89, 137.46	
	Median	96.46		114.86		87.60	
	Q25, Q75	63.41, 141.04		76.45, 148.06		66.26, 150.52	
	Min, Max	12.4, 685.4		26.3, 299.3		55.3, 267.2	
	Mean (SD)	115.89 (107.233)		124.64 (66.089)		113.37 (62.692)	
	95% CI of Mean	80.13, 151.65		99.50, 149.78		73.53, 153.21	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	37	33	29	13	12
	Missing, n (%)	0	3 (7.5)	1 (2.9)	5 (14.7)	0	1 (7.7)
	BLOQ, n(%)	28 (70.0)		8 (24.2)		9 (69.2)	
	Geometric Mean (CV%)	44.69 (76.104)		98.59 (57.191)		43.04 (57.757)	
	95% CI of Geometric Mean	36.00, 55.49		81.63, 119.06		31.12, 59.53	
	Median	38.00	-57.43	93.39	-3.07	44.33	-66.32
	Q25, Q75	29.14, 62.87	-72.44, -21.52	69.82, 157.73	-38.48, 34.22	26.60, 71.84	-72.30, -43.78
	Min, Max	16.4, 624.3	-96.0, 1465.9	35.0, 253.6	-60.8, 316.8	19.7, 94.2	-77.7, 19.2
	Mean (SD)	62.78 (95.540)	-1.39 (251.901)	112.35 (56.990)	7.00 (73.048)	48.95 (25.031)	-51.47 (34.017)
	95% CI of Mean	32.22, 93.34	-85.38, 82.60	92.13, 132.56	-20.79, 34.79	33.82, 64.08	-73.09, -29.85

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	35		30		11	
	Missing, n (%)	4 (10.3)		5 (14.3)		1 (8.3)	
	BLOQ, n(%)	9 (25.7)		5 (16.7)		3 (27.3)	
	Geometric Mean (CV%)	98.59 (74.463)		109.76 (60.001)		84.21 (49.106)	
	95% CI of Geometric Mean	78.47, 123.86		89.22, 135.01		61.62, 115.08	
	Median	110.15		115.16		81.42	
	Q25, Q75	67.09, 141.04		76.45, 158.54		62.50, 143.69	
	Min, Max	12.4, 685.4		26.3, 299.3		40.1, 176.1	
	Mean (SD)	122.35 (107.752)		125.77 (65.234)		93.11 (45.177)	
	95% CI of Mean	85.33, 159.37		101.41, 150.13		62.75, 123.46	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	35	34	30	11	11
	Missing, n (%)	0	4 (10.3)	1 (2.9)	5 (14.3)	1 (8.3)	1 (8.3)
	BLOQ, n(%)	29 (74.4)		6 (17.6)		6 (54.5)	
	Geometric Mean (CV%)	42.39 (54.727)		99.95 (64.139)		42.03 (58.333)	
	95% CI of Geometric Mean	35.90, 50.04		81.43, 122.67		29.21, 60.46	
	Median	40.92	-57.36	113.94	-5.67	37.31	-51.72
	Q25, Q75	30.49, 63.94	-75.62, -19.06	57.74, 153.13	-23.98, 31.17	26.21, 60.30	-67.81, -36.21
	Min, Max	13.5, 111.4	-94.8, 119.2	33.2, 274.5	-71.4, 75.0	19.4, 114.1	-75.1, 78.6
	Mean (SD)	47.88 (23.561)	-43.77 (46.174)	117.04 (65.009)	1.37 (36.379)	48.34 (28.831)	-41.38 (42.698)
	95% CI of Mean	40.24, 55.53	-59.63, -27.90	94.35, 139.73	-12.22, 14.96	28.97, 67.72	-70.07, -12.69

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	43		29		9	
	Missing, n (%)	4 (8.5)		3 (9.4)		0	
	BLOQ, n(%)	12 (27.9)		5 (17.2)		3 (33.3)	
	Geometric Mean (CV%)	98.98 (73.685)		109.34 (61.189)		77.58 (46.332)	
	95% CI of Geometric Mean	80.81, 121.22		88.23, 135.51		55.27, 108.88	
	Median	115.79		114.86		68.61	
	Q25, Q75	66.49, 141.26		76.45, 158.54		62.50, 90.87	
	Min, Max	12.4, 685.4		26.3, 299.3		40.1, 157.3	
	Mean (SD)	122.02 (101.003)		125.88 (66.386)		84.86 (40.063)	
	95% CI of Mean	90.93, 153.11		100.63, 151.14		54.07, 115.66	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	43	32	29	9	9
	Missing, n (%)	0	4 (8.5)	0	3 (9.4)	0	
	BLOQ, n(%)	34 (72.3)		7 (21.9)		7 (77.8)	
	Geometric Mean (CV%)	47.53 (75.733)		107.39 (76.202)		37.30 (35.623)	
	95% CI of Geometric Mean	39.00, 57.92		84.14, 137.07		28.60, 48.66	
	Median	40.06	-52.19	115.72	6.51	30.12	-50.76
	Q25, Q75	29.24, 66.85	-76.21, -21.68	66.34, 162.24	-30.95, 25.51	28.25, 48.46	-67.30, -29.37
	Min, Max	19.4, 961.5	-96.1, 896.8	30.2, 686.7	-56.8, 275.0	26.6, 65.3	-79.5, -11.5
	Mean (SD)	70.42 (136.108)	-20.76 (149.681)	136.05 (118.289)	10.33 (60.000)	39.41 (14.348)	-46.88 (23.465)
	95% CI of Mean	30.45, 110.39	-66.83, 25.31	93.39, 178.70	-12.50, 33.15	28.38, 50.45	-64.92, -28.84

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	70	31	22
	Missing, n (%)	5 (6.7)	4 (11.4)	2 (8.3)
	BLOQ, n(%)	18 (25.7)	5 (16.1)	5 (22.7)
	Geometric Mean (CV%)	164.22 (66.689)	185.64 (56.455)	151.78 (62.668)
	95% CI of Geometric Mean	142.11, 189.79	153.06, 225.15	117.59, 195.90
	Median	182.24	186.48	158.29
	Q25, Q75	105.53, 241.56	146.70, 299.03	107.02, 234.00
	Min, Max	30.8, 771.9	32.9, 378.1	39.5, 338.2
	Mean (SD)	194.89 (120.366)	207.74 (89.902)	174.57 (86.621)
	95% CI of Mean	166.18, 223.59	174.76, 240.73	136.16, 212.98

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	51 (68.9)	6 (17.1)	11 (47.8)
	Geometric Mean (CV%)	70.64 (47.615)	170.71 (55.187)	69.78 (49.235)
	95% CI of Geometric Mean	63.61, 78.44	143.00, 203.80	57.05, 85.36
	Median	67.30	172.34	65.82
	Q25, Q75	50.43, 98.82	123.90, 240.83	51.88, 80.77
	Min, Max	25.2, 172.9	49.3, 492.9	37.5, 261.1
	Mean (SD)	78.16 (36.470)	192.97 (97.392)	78.85 (48.849)
	95% CI of Mean	69.71, 86.62	159.51, 226.43	57.72, 99.97

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	60 (81.1)	11 (31.4)	17 (73.9)
	Geometric Mean (CV%)	61.81 (47.050)	152.88 (75.705)	56.39 (37.847)
	95% CI of Geometric Mean	55.72, 68.56	121.31, 192.65	48.14, 66.07
	Median	57.73	164.92	58.90
	Q25, Q75	47.03, 79.13	85.35, 256.71	43.98, 67.94
	Min, Max	26.2, 279.5	39.1, 544.0	27.8, 139.7
	Mean (SD)	69.10 (39.722)	186.17 (111.884)	60.31 (24.455)
	95% CI of Mean	59.89, 78.30	147.73, 224.61	49.73, 70.89

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	51 (68.9)	6 (17.1)	14 (60.9)
	Geometric Mean (CV%)	69.52 (48.636)	192.39 (57.871)	62.52 (60.289)
	95% CI of Geometric Mean	62.48, 77.36	159.95, 231.40	49.13, 79.54
	Median	67.81	210.59	62.15
	Q25, Q75	47.28, 98.97	129.19, 264.42	39.18, 88.90
	Min, Max	27.5, 199.0	47.5, 663.9	20.3, 184.8
	Mean (SD)	77.35 (37.637)	218.72 (113.572)	72.16 (39.953)
	95% CI of Mean	68.62, 86.07	179.70, 257.74	54.87, 89.44

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	54 (73.0)	5 (14.3)	17 (73.9)
	Geometric Mean (CV%)	62.98 (45.454)	168.22 (51.364)	56.42 (57.865)
	95% CI of Geometric Mean	56.96, 69.63	142.45, 198.65	44.72, 71.19
	Median	60.39	183.35	54.88
	Q25, Q75	47.98, 88.28	120.96, 234.31	36.10, 75.16
	Min, Max	23.6, 193.3	56.1, 402.5	21.3, 251.6
	Mean (SD)	69.22 (32.146)	187.13 (85.364)	66.08 (47.235)
	95% CI of Mean	61.77, 76.67	157.80, 216.45	45.65, 86.51

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	69 (93.2)	13 (37.1)	20 (87.0)
	Geometric Mean (CV%)	72.20 (43.339)	154.15 (57.998)	57.01 (50.975)
	95% CI of Geometric Mean	65.58, 79.49	128.11, 185.47	46.31, 70.19
	Median	68.99	147.89	56.65
	Q25, Q75	51.90, 96.47	98.98, 225.13	44.93, 68.90
	Min, Max	29.2, 211.8	54.1, 450.1	22.2, 233.0
	Mean (SD)	78.86 (35.867)	177.08 (95.481)	64.92 (43.088)
	95% CI of Mean	70.54, 87.17	144.28, 209.89	46.29, 83.56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (ng)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	38	30	12
	Missing, n (%)	2 (5.0)	4 (11.8)	1 (7.7)
	BLOQ, n(%)	12 (31.6)	5 (16.7)	2 (16.7)
	Geometric Mean (CV%)	151.02 (73.281)	181.83 (57.657)	157.89 (45.021)
	95% CI of Geometric Mean	121.74, 187.35	148.86, 222.11	120.17, 207.45
	Median	179.60	175.37	151.57
	Q25, Q75	81.70, 241.56	137.70, 299.03	121.00, 225.39
	Min, Max	30.8, 771.9	32.9, 378.1	72.5, 300.5
	Mean (SD)	185.41 (133.501)	204.71 (92.259)	171.58 (72.983)
	95% CI of Mean	141.53, 229.30	170.26, 239.17	125.21, 217.96

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (ng)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Day 30	n	40	34	13
	BLOQ, n(%)	28 (70.0)	8 (23.5)	9 (69.2)
	Geometric Mean (CV%)	72.42 (74.000)	165.56 (55.289)	70.70 (64.528)
	95% CI of Geometric Mean	58.62, 89.46	138.26, 198.26	49.49, 100.99
	Median	59.43	178.59	56.25
	Q25, Q75	45.25, 98.24	117.94, 235.82	48.03, 91.85
	Min, Max	32.6, 844.4	59.9, 402.5	31.1, 220.1
	Mean (SD)	99.23 (134.075)	186.37 (87.174)	84.02 (56.100)
	95% CI of Mean	56.34, 142.11	155.95, 216.79	50.11, 117.92

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (ng)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	37	31	12
	Missing, n (%)	2 (5.1)	4 (11.4)	0
	BLOQ, n(%)	9 (24.3)	5 (16.1)	3 (25.0)
	Geometric Mean (CV%)	162.68 (73.167)	182.78 (56.643)	137.58 (49.136)
	95% CI of Geometric Mean	130.77, 202.37	150.62, 221.80	102.38, 184.87
	Median	197.80	175.60	137.30
	Q25, Q75	97.65, 245.94	137.70, 299.03	107.69, 192.03
	Min, Max	30.8, 771.9	32.9, 378.1	59.9, 300.5
	Mean (SD)	197.72 (133.394)	205.00 (90.722)	151.47 (69.361)
	95% CI of Mean	153.24, 242.20	171.71, 238.28	107.40, 195.55

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (ng)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Day 60	n	39	35	12
	BLOQ, n(%)	29 (74.4)	6 (17.1)	7 (58.3)
	Geometric Mean (CV%)	68.85 (56.271)	168.28 (58.338)	68.88 (60.275)
	95% CI of Geometric Mean	58.08, 81.61	139.73, 202.67	48.35, 98.11
	Median	62.20	184.68	55.49
	Q25, Q75	49.45, 91.10	120.37, 263.23	43.26, 111.36
	Min, Max	18.2, 221.9	51.7, 415.3	36.2, 183.4
	Mean (SD)	79.52 (48.421)	191.53 (92.919)	80.20 (49.495)
	95% CI of Mean	63.81, 95.22	159.61, 223.45	48.75, 111.65

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (ng)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	45	29	9
	Missing, n (%)	2 (4.3)	3 (9.4)	0
	BLOQ, n(%)	12 (26.7)	5 (17.2)	3 (33.3)
	Geometric Mean (CV%)	161.24 (73.548)	178.89 (57.064)	125.82 (48.358)
	95% CI of Geometric Mean	132.33, 196.46	146.17, 218.93	88.45, 178.97
	Median	189.34	175.14	136.13
	Q25, Q75	92.19, 245.94	137.70, 285.60	100.85, 164.69
	Min, Max	30.8, 771.9	32.9, 378.1	59.9, 231.4
	Mean (SD)	196.90 (132.879)	200.84 (89.262)	137.54 (59.568)
	95% CI of Mean	156.97, 236.83	166.88, 234.80	91.74, 183.33

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.1 Descriptive Statistics of o-tol in 24-hour Urine Collection - PP Set****Parameter (units): o-tol (ng)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Day 90	n	47	32	9
	BLOQ, n(%)	34 (72.3)	7 (21.9)	7 (77.8)
	Geometric Mean (CV%)	79.75 (69.373)	178.31 (73.365)	63.86 (51.653)
	95% CI of Geometric Mean	66.34, 95.87	140.74, 225.91	43.93, 92.80
	Median	71.90	188.17	63.30
	Q25, Q75	51.33, 100.09	113.41, 256.61	42.55, 89.90
	Min, Max	37.2, 1254.8	62.3, 1320.8	34.7, 151.3
	Mean (SD)	109.93 (177.319)	226.96 (221.311)	71.24 (37.393)
	95% CI of Mean	57.86, 161.99	147.16, 306.76	42.49, 99.99

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		36		36	
	Missing, n (%)	9 (11.3)		5 (12.2)		3 (7.7)	
	BLOQ, n(%)	18 (25.4)		6 (16.7)		8 (22.2)	
	Geometric Mean (CV%)	98.70 (63.952)		115.97 (60.328)		99.63 (58.284)	
	95% CI of Geometric Mean	85.92, 113.38		96.05, 140.04		82.97, 119.64	
	Median	105.64		118.98		115.55	
	Q25, Q75	69.25, 147.21		78.57, 175.57		67.38, 145.15	
	Min, Max	12.4, 685.4		26.3, 299.3		23.8, 267.2	
	Mean (SD)	116.51 (83.459)		133.14 (68.641)		113.38 (56.042)	
	95% CI of Mean	96.75, 136.27		109.91, 156.37		94.42, 132.35	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	52 (67.5)		7 (17.5)		17 (45.9)	
	Geometric Mean (CV%)	43.04 (51.969)		105.38 (59.447)		47.56 (67.092)	
	95% CI of Geometric Mean	38.51, 48.09		88.38, 125.66		38.81, 58.29	
	Median	39.75	-59.91	107.70	-11.53	42.97	-59.78
	Q25, Q75	31.06, 58.82	-72.44, -29.70	66.54, 160.34	-26.02, 7.36	28.04, 66.14	-71.91, -16.20
	Min, Max	14.0, 206.9	-86.2, 99.0	31.8, 312.5	-45.1, 140.3	18.9, 142.9	-86.0, 272.0
	Mean (SD)	48.83 (28.619)	-48.31 (34.044)	121.64 (66.800)	-1.48 (39.755)	57.50 (38.166)	-38.80 (62.126)
	95% CI of Mean	42.33, 55.33	-56.37, -40.25	100.27, 143.01	-14.94, 11.97	44.77, 70.23	-59.82, -17.77

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	61 (79.2)		11 (27.5)		24 (64.9)	
	Geometric Mean (CV%)	37.59 (46.875)		97.94 (72.943)		40.10 (73.625)	
	95% CI of Geometric Mean	33.97, 41.60		79.47, 120.70		32.19, 49.94	
	Median	38.40	-63.11	107.50	-5.11	37.54	-67.27
	Q25, Q75	27.35, 47.73	-76.59, -36.52	65.15, 161.44	-38.88, 10.16	28.54, 59.42	-75.26, -12.04
	Min, Max	15.3, 152.8	-88.6, 58.0	17.9, 277.0	-77.6, 196.3	10.3, 137.2	-88.6, 121.7
	Mean (SD)	41.91 (23.469)	-52.47 (32.663)	117.49 (66.825)	1.16 (56.806)	49.55 (34.388)	-46.65 (44.281)
	95% CI of Mean	36.58, 47.24	-60.21, -44.74	96.11, 138.87	-18.07, 20.38	38.08, 61.02	-61.64, -31.66

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	54 (70.1)		7 (17.5)		22 (59.5)	
	Geometric Mean (CV%)	41.18 (41.142)		118.51 (61.531)		43.87 (68.730)	
	95% CI of Geometric Mean	37.64, 45.05		98.86, 142.06		35.65, 53.98	
	Median	42.02	-59.30	127.45	0.42	39.35	-60.75
	Q25, Q75	30.71, 53.08	-74.13, -32.30	78.98, 169.36	-25.14, 16.82	25.83, 69.41	-75.03, -1.70
	Min, Max	16.7, 102.2	-90.0, 34.0	28.9, 428.6	-48.9, 287.5	11.3, 137.2	-91.0, 74.0
	Mean (SD)	44.43 (17.735)	-50.10 (31.533)	137.58 (77.789)	13.74 (66.689)	53.06 (34.598)	-45.13 (39.392)
	95% CI of Mean	40.40, 48.46	-57.57, -42.64	112.69, 162.46	-8.83, 36.31	41.52, 64.60	-58.47, -31.80

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	56 (72.7)		6 (15.0)		26 (70.3)	
	Geometric Mean (CV%)	37.60 (41.619)		106.41 (50.887)		39.96 (74.929)	
	95% CI of Geometric Mean	34.33, 41.17		91.27, 124.07		31.98, 49.93	
	Median	37.54	-64.13	110.86	-4.02	34.72	-68.96
	Q25, Q75	28.22, 48.52	-76.48, -43.59	79.73, 150.78	-23.59, 13.82	23.81, 66.14	-78.74, -6.91
	Min, Max	16.3, 122.2	-88.1, 140.4	38.2, 277.0	-55.3, 216.1	10.2, 137.2	-88.8, 53.8
	Mean (SD)	40.82 (18.232)	-52.52 (37.797)	118.50 (55.367)	3.19 (48.686)	49.66 (34.554)	-46.18 (42.143)
	95% CI of Mean	36.68, 44.96	-61.47, -43.57	100.79, 136.22	-13.29, 19.67	38.13, 61.18	-60.45, -31.92

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	71 (92.2)		15 (37.5)		29 (78.4)	
	Geometric Mean (CV%)	42.86 (49.239)		95.93 (56.682)		41.79 (72.186)	
	95% CI of Geometric Mean	38.56, 47.65		81.02, 113.57		33.67, 51.87	
	Median	41.88	-60.11	88.41	-9.88	41.81	-63.00
	Q25, Q75	29.38, 60.83	-75.03, -23.15	61.35, 143.76	-31.53, 9.13	25.35, 60.00	-73.31, 0.00
	Min, Max	12.4, 136.6	-91.9, 261.2	39.0, 277.0	-76.8, 88.7	9.3, 137.2	-87.9, 50.6
	Mean (SD)	47.82 (23.976)	-41.07 (54.017)	110.23 (61.361)	-9.50 (35.062)	51.31 (34.954)	-45.72 (40.300)
	95% CI of Mean	42.37, 53.26	-53.86, -28.28	90.60, 129.85	-21.37, 2.37	39.65, 62.97	-59.36, -32.07

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	52 (67.5)		8 (20.0)		19 (51.4)	
	Geometric Mean (CV%)	45.54 (62.519)		105.30 (55.942)		50.96 (64.342)	
	95% CI of Geometric Mean	39.97, 51.89		89.11, 124.43		41.87, 62.01	
	Median	42.02	-60.72	117.21	-3.06	47.35	-56.44
	Q25, Q75	29.59, 64.10	-72.15, -33.33	74.29, 156.36	-37.74, 33.58	28.80, 76.19	-68.09, -1.56
	Min, Max	16.4, 624.3	-96.0, 1465.9	35.0, 277.0	-60.8, 316.8	18.1, 137.2	-81.7, 134.5
	Mean (SD)	57.32 (70.834)	-24.96 (183.502)	119.29 (58.736)	5.69 (67.585)	59.99 (34.339)	-37.98 (43.671)
	95% CI of Mean	41.24, 73.40	-68.40, 18.48	100.50, 138.08	-17.19, 28.56	48.54, 71.45	-52.76, -23.20

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	53 (68.8)		7 (17.5)		17 (45.9)	
	Geometric Mean (CV%)	43.38 (51.211)		105.07 (62.734)		53.36 (77.949)	
	95% CI of Geometric Mean	38.88, 48.41		87.38, 126.33		42.41, 67.15	
	Median	41.05	-56.48	118.04	-1.53	54.13	-44.56
	Q25, Q75	31.21, 62.34	-73.85, -29.56	64.24, 153.99	-24.16, 27.93	35.28, 89.21	-69.98, 0.00
	Min, Max	13.5, 133.5	-94.8, 119.2	33.2, 277.0	-71.4, 75.0	16.2, 225.9	-86.8, 132.3
	Mean (SD)	48.71 (24.786)	-46.86 (37.261)	122.21 (65.884)	0.28 (34.843)	66.88 (46.997)	-31.50 (49.713)
	95% CI of Mean	43.08, 54.34	-55.69, -38.04	101.13, 143.29	-11.51, 12.07	51.20, 82.55	-48.32, -14.67

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	51 (66.2)		7 (17.5)		20 (54.1)	
	Geometric Mean (CV%)	47.35 (65.343)		114.15 (70.709)		49.85 (59.081)	
	95% CI of Geometric Mean	41.35, 54.22		93.11, 139.94		41.54, 59.84	
	Median	44.72	-51.67	127.56	4.49	48.46	-48.84
	Q25, Q75	32.13, 65.38	-72.60, -26.13	71.95, 160.31	-23.70, 26.17	30.41, 74.60	-66.56, -18.42
	Min, Max	19.4, 961.5	-96.1, 896.8	30.2, 686.7	-56.8, 275.0	22.5, 137.2	-90.8, 33.2
	Mean (SD)	63.29 (107.352)	-30.80 (117.843)	139.83 (108.573)	11.74 (58.179)	57.98 (33.820)	-41.41 (30.885)
	95% CI of Mean	38.92, 87.66	-58.70, -2.91	105.10, 174.56	-7.95, 31.43	46.70, 69.26	-51.87, -30.96

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	74	37	37
	Missing, n (%)	6 (7.5)	4 (9.8)	2 (5.1)
	BLOQ, n(%)	18 (24.3)	6 (16.2)	8 (21.6)
	Geometric Mean (CV%)	165.28 (65.031)	188.64 (54.443)	162.73 (58.545)
	95% CI of Geometric Mean	144.03, 189.66	159.16, 223.57	135.78, 195.02
	Median	182.24	189.10	164.76
	Q25, Q75	108.93, 241.56	146.70, 285.60	120.63, 258.63
	Min, Max	30.8, 771.9	32.9, 378.1	39.5, 344.4
	Mean (SD)	194.75 (117.773)	209.91 (88.300)	184.72 (85.923)
	95% CI of Mean	167.46, 222.04	180.47, 239.36	156.07, 213.37

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 1	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	53 (67.9)	7 (17.1)	18 (47.4)
	Geometric Mean (CV%)	70.36 (46.384)	172.47 (53.725)	77.77 (59.557)
	95% CI of Geometric Mean	63.69, 77.73	147.12, 202.19	64.88, 93.22
	Median	67.30	184.45	68.84
	Q25, Q75	53.41, 98.80	130.22, 240.83	51.88, 119.45
	Min, Max	25.2, 172.9	49.3, 492.9	34.7, 305.8
	Mean (SD)	77.54 (35.660)	193.73 (93.930)	92.12 (64.366)
	95% CI of Mean	69.49, 85.58	164.08, 223.38	70.96, 113.29

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 2	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	62 (79.5)	11 (26.8)	25 (65.8)
	Geometric Mean (CV%)	62.11 (46.246)	162.03 (71.553)	66.01 (63.874)
	95% CI of Geometric Mean	56.24, 68.60	132.27, 198.50	54.46, 80.00
	Median	59.26	190.64	60.88
	Q25, Q75	47.03, 79.13	124.85, 256.71	44.40, 88.28
	Min, Max	26.2, 279.5	39.1, 544.0	19.4, 305.8
	Mean (SD)	69.17 (38.902)	193.15 (106.798)	79.72 (60.105)
	95% CI of Mean	60.39, 77.94	159.43, 226.86	59.96, 99.48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 3	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	55 (70.5)	7 (17.1)	23 (60.5)
	Geometric Mean (CV%)	68.02 (48.723)	193.79 (55.292)	69.58 (70.116)
	95% CI of Geometric Mean	61.30, 75.49	164.64, 228.11	56.51, 85.65
	Median	64.95	222.16	72.21
	Q25, Q75	45.18, 98.30	165.59, 264.42	42.80, 95.34
	Min, Max	27.5, 199.0	47.5, 663.9	20.3, 305.8
	Mean (SD)	75.77 (37.351)	218.07 (107.375)	85.42 (62.439)
	95% CI of Mean	67.35, 84.20	184.18, 251.97	64.89, 105.94

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 4	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	57 (73.1)	6 (14.6)	27 (71.1)
	Geometric Mean (CV%)	62.31 (45.044)	172.96 (48.619)	63.44 (72.901)
	95% CI of Geometric Mean	56.55, 68.65	149.55, 200.03	51.18, 78.62
	Median	60.39	186.32	56.03
	Q25, Q75	47.98, 87.15	130.80, 234.31	38.83, 85.08
	Min, Max	23.6, 193.3	56.1, 402.5	21.3, 305.8
	Mean (SD)	68.40 (31.656)	190.32 (81.120)	80.35 (66.953)
	95% CI of Mean	61.26, 75.54	164.72, 215.93	58.34, 102.36

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 5	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	72 (92.3)	15 (36.6)	30 (78.9)
	Geometric Mean (CV%)	73.20 (43.316)	159.97 (58.699)	70.64 (66.669)
	95% CI of Geometric Mean	66.66, 80.38	134.72, 189.95	57.87, 86.23
	Median	69.66	167.87	62.39
	Q25, Q75	54.08, 96.47	100.40, 243.08	47.18, 102.88
	Min, Max	29.2, 211.8	54.1, 450.1	22.2, 305.8
	Mean (SD)	79.92 (36.142)	183.98 (97.171)	86.31 (64.787)
	95% CI of Mean	71.77, 88.08	153.31, 214.66	65.01, 107.61

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	53 (67.9)	8 (19.5)	20 (52.6)
	Geometric Mean (CV%)	74.34 (61.998)	167.78 (53.609)	82.96 (63.913)
	95% CI of Geometric Mean	65.36, 84.54	143.16, 196.63	68.44, 100.57
	Median	72.35	185.49	80.51
	Q25, Q75	46.93, 108.25	122.26, 235.82	54.40, 121.00
	Min, Max	26.1, 844.4	59.9, 402.5	31.1, 305.8
	Mean (SD)	91.99 (99.069)	187.40 (82.993)	98.77 (64.293)
	95% CI of Mean	69.65, 114.33	161.20, 213.60	77.63, 119.91

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	54 (69.2)	7 (17.1)	18 (47.4)
	Geometric Mean (CV%)	70.10 (53.766)	171.91 (55.097)	89.22 (84.304)
	95% CI of Geometric Mean	62.57, 78.54	146.12, 202.26	70.12, 113.53
	Median	64.86	184.68	87.87
	Q25, Q75	50.50, 95.58	122.11, 263.23	48.68, 152.16
	Min, Max	18.2, 221.9	51.7, 415.3	20.2, 461.9
	Mean (SD)	79.69 (43.598)	193.23 (88.487)	117.72 (99.839)
	95% CI of Mean	69.85, 89.52	165.29, 221.16	84.90, 150.54

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.12.2 Descriptive Statistics of o-tol in 24-hour Urine Collection - FAS****Parameter (units): o-tol (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	52 (66.7)	7 (17.1)	21 (55.3)
	Geometric Mean (CV%)	79.53 (61.859)	181.14 (64.586)	80.57 (67.329)
	95% CI of Geometric Mean	69.95, 90.43	150.33, 218.25	65.90, 98.51
	Median	72.49	193.19	83.87
	Q25, Q75	54.95, 112.33	141.54, 251.35	43.95, 122.58
	Min, Max	26.9, 1254.8	62.3, 1320.8	34.7, 305.8
	Mean (SD)	101.17 (139.687)	220.43 (196.383)	97.19 (64.568)
	95% CI of Mean	69.67, 132.67	158.44, 282.42	75.96, 118.42

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set****Parameter (units): CEMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		30		21	
	Missing, n (%)	8 (10.7)		5 (14.3)		3 (12.5)	
	Geometric Mean (CV%)	90.62 (63.691)		99.50 (60.890)		91.97 (69.000)	
	95% CI of Geometric Mean	78.59, 104.48		80.67, 122.71		69.22, 122.18	
	Median	94.56		99.84		96.37	
	Q25, Q75	70.08, 132.48		80.77, 144.99		79.10, 142.65	
	Min, Max	14.5, 317.1		19.6, 322.7		13.1, 205.8	
	Mean (SD)	104.88 (54.859)		114.12 (60.947)		106.37 (51.085)	
	95% CI of Mean	91.49, 118.27		91.36, 136.88		83.12, 129.63	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set****Parameter (units): CEMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	30.67 (67.157)		90.79 (62.140)		32.76 (61.740)	
	95% CI of Geometric Mean	26.60, 35.37		74.37, 110.82		25.46, 42.16	
	Median	30.84	-67.46	94.28	-6.12	33.18	-61.27
	Q25, Q75	21.25, 50.24	-75.66, -54.69	69.32, 123.36	-21.82, 13.04	24.33, 44.30	-74.00, -55.25
	Min, Max	5.7, 219.5	-83.7, 0.0	15.6, 322.7	-49.3, 50.1	10.9, 91.2	-76.6, -12.1
	Mean (SD)	37.03 (28.175)	-63.51 (16.076)	105.27 (60.406)	-5.88 (25.060)	38.16 (22.344)	-61.33 (15.102)
	95% CI of Mean	30.45, 43.60	-67.44, -59.59	84.19, 126.36	-15.25, 3.48	28.25, 48.08	-68.21, -54.45

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set****Parameter (units): CEMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	17.92 (63.417)		84.30 (62.666)		19.77 (89.176)	
	95% CI of Geometric Mean	15.65, 20.53		68.96, 103.06		14.08, 27.76	
	Median	19.53	-79.74	95.25	-15.90	21.16	-79.78
	Q25, Q75	14.44, 26.96	-83.57, -75.70	56.24, 119.09	-25.74, 3.06	12.05, 31.57	-82.18, -74.05
	Min, Max	3.6, 61.6	-93.0, -48.0	15.6, 322.7	-55.1, 72.2	2.2, 80.0	-88.3, -51.4
	Mean (SD)	20.74 (10.594)	-78.80 (8.029)	97.77 (56.134)	-10.34 (25.178)	25.24 (18.133)	-76.88 (8.917)
	95% CI of Mean	18.26, 23.21	-80.77, -76.84	78.18, 117.36	-19.75, -0.93	17.20, 33.28	-80.95, -72.82

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set****Parameter (units): CEMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	16.96 (66.091)		92.20 (63.553)		17.31 (77.299)	
	95% CI of Geometric Mean	14.73, 19.52		75.24, 112.98		12.77, 23.45	
	Median	18.54	-80.83	97.56	-8.76	16.64	-83.28
	Q25, Q75	14.17, 24.67	-85.71, -77.04	71.11, 129.17	-20.45, 10.88	11.63, 25.17	-86.44, -74.56
	Min, Max	2.1, 49.7	-94.7, -59.3	14.9, 322.7	-45.2, 40.0	5.5, 84.9	-88.9, -48.4
	Mean (SD)	19.72 (10.090)	-80.35 (7.103)	107.17 (60.968)	-5.09 (23.262)	21.97 (17.955)	-79.51 (10.471)
	95% CI of Mean	17.36, 22.08	-82.09, -78.61	85.90, 128.45	-13.79, 3.60	14.00, 29.93	-84.28, -74.74

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set****Parameter (units): CEMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	15.14 (71.926)		89.90 (60.303)		15.07 (79.066)	
	95% CI of Geometric Mean	13.02, 17.61		74.02, 109.18		11.06, 20.53	
	Median	15.65	-83.43	85.48	-4.50	14.94	-84.93
	Q25, Q75	11.56, 21.88	-87.45, -78.72	68.88, 118.71	-18.40, 2.60	10.68, 23.68	-87.93, -79.30
	Min, Max	2.6, 54.0	-94.1, -48.8	15.3, 322.7	-69.7, 79.0	4.8, 74.3	-91.3, -54.9
	Mean (SD)	18.10 (10.424)	-81.71 (8.773)	103.59 (59.168)	-5.00 (26.264)	19.19 (15.591)	-81.94 (9.796)
	95% CI of Mean	15.66, 20.54	-83.86, -79.57	82.94, 124.24	-14.81, 4.81	12.27, 26.11	-86.41, -77.48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set****Parameter (units): CEMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	14.39 (75.405)		88.40 (65.649)		13.40 (72.027)	
	95% CI of Geometric Mean	12.30, 16.83		71.73, 108.94		10.06, 17.86	
	Median	15.52	-84.22	91.22	-13.10	12.57	-86.87
	Q25, Q75	11.90, 20.83	-87.86, -80.69	65.21, 130.93	-25.73, 4.50	8.67, 21.12	-88.55, -82.35
	Min, Max	2.1, 52.3	-95.0, -45.6	11.2, 322.7	-62.3, 103.9	4.4, 70.2	-94.4, -57.3
	Mean (SD)	17.40 (10.374)	-83.00 (8.334)	102.62 (56.627)	-9.05 (28.525)	16.78 (14.207)	-83.83 (9.194)
	95% CI of Mean	14.97, 19.82	-85.04, -80.96	82.86, 122.39	-19.71, 1.60	10.47, 23.08	-88.02, -79.64

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set****Parameter (units): CEMA (ng/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		29		12	
	Missing, n (%)	3 (7.5)		5 (14.7)		1 (7.7)	
	Geometric Mean (CV%)	91.53 (65.100)		91.92 (60.828)		98.62 (49.558)	
	95% CI of Geometric Mean	75.07, 111.60		74.25, 113.79		73.22, 132.83	
	Median	91.82		98.18		105.38	
	Q25, Q75	66.56, 147.96		75.73, 125.03		70.18, 140.95	
	Min, Max	20.6, 317.1		19.6, 235.1		44.0, 203.9	
	Mean (SD)	107.31 (60.573)		104.60 (49.294)		108.55 (48.239)	
	95% CI of Mean	87.11, 127.51		85.84, 123.35		77.89, 139.20	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set****Parameter (units): CEMA (ng/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	37	33	29	13	12
	Missing, n (%)	0	3 (7.5)	1 (2.9)	5 (14.7)	0	1 (7.7)
	Geometric Mean (CV%)	19.00 (114.963)		93.88 (65.778)		20.06 (138.705)	
	95% CI of Geometric Mean	14.16, 25.48		75.89, 116.12		10.72, 37.52	
	Median	19.41	-80.05	90.80	8.05	21.98	-73.44
	Q25, Q75	10.24, 37.49	-90.03, -62.40	67.33, 131.14	-22.71, 26.48	8.23, 34.45	-93.08, -64.82
	Min, Max	2.1, 139.5	-96.9, 52.7	19.1, 283.5	-47.6, 251.0	4.0, 142.9	-93.6, -13.2
	Mean (SD)	27.78 (26.794)	-71.01 (29.516)	110.53 (64.519)	11.55 (55.524)	32.49 (36.971)	-71.73 (25.117)
	95% CI of Mean	19.21, 36.35	-80.86, -61.17	87.65, 133.41	-9.57, 32.68	10.14, 54.84	-87.69, -55.77

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set****Parameter (units): CEMA (ng/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	35		30		11	
	Missing, n (%)	4 (10.3)		5 (14.3)		1 (8.3)	
	Geometric Mean (CV%)	88.51 (70.280)		92.19 (59.630)		81.20 (82.417)	
	95% CI of Geometric Mean	71.20, 110.04		75.03, 113.28		50.05, 131.71	
	Median	91.82		98.70		96.37	
	Q25, Q75	66.56, 139.38		75.73, 125.03		61.25, 128.37	
	Min, Max	14.5, 317.1		19.6, 235.1		13.1, 164.5	
	Mean (SD)	104.75 (59.504)		104.46 (48.443)		96.19 (45.756)	
	95% CI of Mean	84.31, 125.20		86.36, 122.55		65.45, 126.94	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set****Parameter (units): CEMA (ng/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	35	34	30	11	11
	Missing, n (%)	0	4 (10.3)	1 (2.9)	5 (14.3)	1 (8.3)	1 (8.3)
	Geometric Mean (CV%)	15.13 (115.855)		84.55 (72.327)		16.94 (204.384)	
	95% CI of Geometric Mean	11.22, 20.41		67.42, 106.03		7.15, 40.09	
	Median	15.62	-84.24	97.22	-4.14	21.47	-67.25
	Q25, Q75	7.71, 28.32	-92.52, -75.22	61.98, 128.91	-27.85, 24.95	5.30, 37.46	-94.51, -51.16
	Min, Max	3.2, 149.4	-97.1, -6.7	14.1, 218.4	-47.1, 89.3	2.6, 135.4	-95.8, -17.7
	Mean (SD)	23.33 (26.771)	-78.22 (20.472)	99.88 (51.634)	0.30 (35.174)	34.16 (42.716)	-67.95 (25.763)
	95% CI of Mean	14.65, 32.02	-85.26, -71.18	81.86, 117.90	-12.84, 13.44	5.45, 62.86	-85.26, -50.64

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set**

Parameter (units): CEMA (ng/mg creat)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	43		29		9	
	Missing, n (%)	4 (8.5)		3 (9.4)		0	
	Geometric Mean (CV%)	92.18 (66.846)		91.35 (60.563)		75.87 (89.862)	
	95% CI of Geometric Mean	76.45, 111.15		73.85, 112.99		41.99, 137.06	
	Median	101.34		98.18		96.37	
	Q25, Q75	69.55, 141.74		75.73, 125.03		61.25, 116.04	
	Min, Max	14.5, 317.1		19.6, 235.1		13.1, 164.5	
	Mean (SD)	107.56 (57.161)		103.91 (49.205)		91.72 (46.338)	
	95% CI of Mean	89.96, 125.15		85.19, 122.63		56.10, 127.34	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set****Parameter (units): CEMA (ng/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	43	32	29	9	9
	Missing, n (%)	0	4 (8.5)	0	3 (9.4)	0	
	Geometric Mean (CV%)	14.12 (157.935)		87.35 (90.340)		13.81 (247.744)	
	95% CI of Geometric Mean	10.16, 19.61		66.11, 115.41		4.70, 40.57	
	Median	14.33	-87.44	107.10	-1.14	23.11	-70.00
	Q25, Q75	5.37, 34.58	-94.74, -64.46	58.26, 137.36	-26.48, 10.57	5.90, 34.31	-95.40, -43.35
	Min, Max	1.1, 121.9	-98.6, -7.7	4.4, 249.5	-77.5, 128.3	1.4, 100.6	-97.7, -20.9
	Mean (SD)	24.62 (26.891)	-76.58 (23.309)	107.53 (61.134)	2.56 (44.253)	27.42 (31.122)	-65.96 (28.761)
	95% CI of Mean	16.71, 32.52	-83.76, -69.40	85.48, 129.57	-14.27, 19.40	3.50, 51.35	-88.08, -43.85

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set**

Parameter (units): CEMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	70	31	22
	Missing, n (%)	5 (6.7)	4 (11.4)	2 (8.3)
	Geometric Mean (CV%)	151.58 (63.991)	160.74 (61.006)	144.94 (68.117)
	95% CI of Geometric Mean	131.81, 174.31	130.77, 197.58	110.23, 190.58
	Median	163.63	172.53	146.68
	Q25, Q75	108.30, 205.87	133.21, 234.23	102.14, 220.02
	Min, Max	29.8, 537.2	22.2, 400.0	19.5, 356.4
	Mean (SD)	178.01 (104.776)	181.98 (83.233)	167.60 (82.829)
	95% CI of Mean	153.02, 202.99	151.45, 212.52	130.87, 204.33

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set**

Parameter (units): CEMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	51.14 (66.291)	149.49 (67.258)	52.48 (65.073)
	95% CI of Geometric Mean	44.46, 58.82	121.19, 184.40	40.58, 67.86
	Median	54.23	144.70	54.67
	Q25, Q75	37.27, 75.59	114.39, 220.94	33.31, 87.52
	Min, Max	11.8, 215.0	19.0, 413.0	15.1, 179.0
	Mean (SD)	60.52 (36.493)	174.28 (92.478)	62.05 (38.331)
	95% CI of Mean	52.06, 68.98	142.51, 206.06	45.47, 78.63

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set**

Parameter (units): CEMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	30.31 (66.727)	139.81 (63.762)	30.99 (80.477)
	95% CI of Geometric Mean	26.33, 34.89	114.39, 170.88	22.83, 42.07
	Median	31.53	147.06	30.54
	Q25, Q75	21.05, 45.76	103.88, 211.55	22.27, 43.19
	Min, Max	6.9, 135.5	16.4, 360.1	4.0, 159.6
	Mean (SD)	35.95 (21.922)	160.33 (78.842)	38.92 (31.294)
	95% CI of Mean	30.86, 41.03	133.24, 187.42	25.39, 52.46

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set**

Parameter (units): CEMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	28.53 (68.180)	152.14 (64.481)	26.09 (78.293)
	95% CI of Geometric Mean	24.72, 32.93	124.24, 186.31	19.34, 35.18
	Median	29.10	164.30	25.86
	Q25, Q75	22.31, 43.66	115.76, 218.81	16.66, 39.05
	Min, Max	4.1, 110.8	14.7, 338.1	7.0, 180.1
	Mean (SD)	33.89 (20.444)	173.45 (79.468)	34.10 (34.826)
	95% CI of Mean	29.15, 38.63	146.14, 200.75	19.03, 49.16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set**

Parameter (units): CEMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	25.64 (72.700)	145.87 (62.444)	23.51 (77.220)
	95% CI of Geometric Mean	22.04, 29.82	119.77, 177.66	17.48, 31.60
	Median	25.83	148.33	22.13
	Q25, Q75	17.50, 39.82	112.84, 214.88	15.00, 33.76
	Min, Max	4.0, 96.9	16.9, 348.9	5.7, 157.3
	Mean (SD)	31.03 (19.461)	166.14 (78.373)	30.25 (29.788)
	95% CI of Mean	26.52, 35.54	139.22, 193.07	17.37, 43.14

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set**

Parameter (units): CEMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	25.09 (79.528)	146.60 (69.521)	22.19 (73.638)
	95% CI of Geometric Mean	21.33, 29.51	118.15, 181.89	16.68, 29.50
	Median	27.36	138.67	20.86
	Q25, Q75	20.19, 38.29	114.50, 248.49	15.27, 31.45
	Min, Max	3.1, 97.5	13.6, 397.2	6.2, 148.7
	Mean (SD)	30.94 (19.702)	170.65 (86.802)	28.46 (28.586)
	95% CI of Mean	26.37, 35.51	140.83, 200.48	16.10, 40.83

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set**

Parameter (units): CEMA (ug)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	38	30	12
	Missing, n (%)	2 (5.0)	4 (11.8)	1 (7.7)
	Geometric Mean (CV%)	149.21 (63.758)	153.90 (64.802)	154.50 (54.095)
	95% CI of Geometric Mean	123.14, 180.79	123.37, 191.99	111.97, 213.17
	Median	165.39	168.99	140.75
	Q25, Q75	87.10, 215.34	118.92, 217.57	104.58, 241.03
	Min, Max	50.6, 509.8	22.2, 400.0	81.0, 356.4
	Mean (SD)	175.03 (101.837)	176.86 (85.876)	174.72 (94.936)
	95% CI of Mean	141.55, 208.51	144.79, 208.93	114.39, 235.04

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set**

Parameter (units): CEMA (ug)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Day 30	n	40	34	13
	Geometric Mean (CV%)	30.78 (128.760)	159.70 (68.904)	32.95 (145.392)
	95% CI of Geometric Mean	22.43, 42.23	128.48, 198.50	17.30, 62.75
	Median	27.96	151.31	41.88
	Q25, Q75	17.06, 61.80	111.09, 232.37	12.15, 55.66
	Min, Max	2.4, 236.1	32.1, 528.2	7.2, 274.9
	Mean (SD)	48.17 (51.861)	190.92 (119.836)	55.43 (70.035)
	95% CI of Mean	31.58, 64.76	149.10, 232.74	13.11, 97.76

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set**

Parameter (units): CEMA (ug)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	37	31	12
	Missing, n (%)	2 (5.1)	4 (11.4)	0
	Geometric Mean (CV%)	144.33 (71.286)	153.27 (63.576)	128.59 (88.268)
	95% CI of Geometric Mean	116.55, 178.72	123.77, 189.79	79.38, 208.28
	Median	165.33	165.45	126.97
	Q25, Q75	87.10, 207.92	118.92, 217.57	99.82, 205.96
	Min, Max	29.8, 509.8	22.2, 400.0	19.5, 356.4
	Mean (SD)	173.32 (104.717)	175.52 (84.762)	159.66 (102.305)
	95% CI of Mean	138.40, 208.24	144.43, 206.62	94.65, 224.67

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set**

Parameter (units): CEMA (ug)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Day 60	n	39	35	12
	Geometric Mean (CV%)	24.58 (121.034)	142.83 (71.281)	27.34 (205.291)
	95% CI of Geometric Mean	18.06, 33.45	114.60, 178.01	12.08, 61.86
	Median	22.02	149.66	32.32
	Q25, Q75	11.97, 39.65	107.13, 204.80	8.55, 61.58
	Min, Max	4.1, 260.9	15.5, 522.9	5.0, 217.5
	Mean (SD)	39.99 (50.189)	169.01 (97.151)	55.51 (68.897)
	95% CI of Mean	23.71, 56.26	135.64, 202.39	11.73, 99.29

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set**

Parameter (units): CEMA (ug)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	45	29	9
	Missing, n (%)	2 (4.3)	3 (9.4)	0
	Geometric Mean (CV%)	148.46 (67.836)	149.45 (64.642)	123.05 (102.543)
	95% CI of Geometric Mean	123.40, 178.61	119.36, 187.12	64.13, 236.09
	Median	176.95	158.82	134.36
	Q25, Q75	104.79, 207.92	118.92, 213.68	98.83, 149.88
	Min, Max	29.8, 509.8	22.2, 400.0	19.5, 356.4
	Mean (SD)	175.57 (100.190)	171.93 (85.281)	159.28 (111.566)
	95% CI of Mean	145.47, 205.68	139.48, 204.37	73.52, 245.04

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.1 Descriptive Statistics of CEMA in 24-hour Urine Collection - PP Set**

Parameter (units): CEMA (ug)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Day 90	n	47	32	9
	Geometric Mean (CV%)	23.69 (165.824)	145.03 (93.610)	23.64 (283.648)
	95% CI of Geometric Mean	16.90, 33.21	108.95, 193.06	7.55, 73.97
	Median	22.58	154.15	50.89
	Q25, Q75	10.97, 51.69	115.79, 220.90	6.33, 54.94
	Min, Max	2.3, 219.7	5.3, 434.8	3.2, 205.4
	Mean (SD)	43.46 (50.857)	178.04 (99.375)	52.25 (63.959)
	95% CI of Mean	28.52, 58.40	142.21, 213.88	3.08, 101.42

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		36		36	
	Missing, n (%)	9 (11.3)		5 (12.2)		3 (7.7)	
	Geometric Mean (CV%)	91.54 (63.606)		102.64 (63.133)		99.29 (66.070)	
	95% CI of Geometric Mean	79.74, 105.08		84.37, 124.86		80.99, 121.72	
	Median	91.82		105.26		106.21	
	Q25, Q75	72.25, 132.48		84.84, 145.47		80.09, 149.54	
	Min, Max	14.5, 317.1		19.6, 322.7		13.1, 215.3	
	Mean (SD)	106.24 (57.378)		118.55 (62.880)		114.30 (53.705)	
	95% CI of Mean	92.65, 119.82		97.27, 139.83		96.13, 132.48	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	30.71 (67.545)		93.86 (61.642)		38.23 (81.004)	
	95% CI of Geometric Mean	26.72, 35.30		78.28, 112.54		30.16, 48.44	
	Median	30.63	-67.46	95.45	-6.12	36.69	-62.34
	Q25, Q75	21.12, 50.24	-75.66, -54.70	71.83, 138.95	-21.44, 10.96	24.33, 69.59	-73.33, -52.67
	Min, Max	5.7, 219.5	-83.7, 0.0	15.6, 322.7	-49.3, 50.1	8.9, 187.6	-84.9, 0.0
	Mean (SD)	37.20 (28.365)	-63.90 (15.757)	108.38 (59.272)	-5.58 (23.823)	48.85 (37.472)	-55.26 (25.871)
	95% CI of Mean	30.75, 43.64	-67.64, -60.17	89.42, 127.34	-13.65, 2.48	36.35, 61.35	-64.02, -46.50

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	18.18 (65.019)		89.66 (62.321)		23.68 (124.190)	
	95% CI of Geometric Mean	15.89, 20.81		74.65, 107.69		17.16, 32.69	
	Median	19.53	-79.74	101.63	-12.79	22.70	-79.77
	Q25, Q75	13.69, 26.96	-83.57, -75.65	60.72, 120.39	-21.41, 5.29	12.05, 46.62	-83.09, -72.62
	Min, Max	3.6, 79.1	-93.0, -48.0	15.6, 322.7	-55.1, 83.7	2.2, 187.6	-94.0, 0.0
	Mean (SD)	21.33 (12.347)	-78.73 (7.931)	103.71 (57.215)	-6.85 (28.314)	36.68 (38.971)	-68.14 (28.906)
	95% CI of Mean	18.52, 24.13	-80.61, -76.85	85.41, 122.01	-16.44, 2.73	23.68, 49.68	-77.93, -58.36

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	17.16 (66.726)		96.10 (63.417)		21.06 (123.483)	
	95% CI of Geometric Mean	14.95, 19.70		79.79, 115.74		15.27, 29.03	
	Median	18.54	-80.83	103.28	-5.97	20.66	-83.09
	Q25, Q75	13.08, 24.67	-85.18, -77.04	71.83, 129.47	-19.94, 15.27	11.63, 34.36	-86.98, -73.74
	Min, Max	2.1, 60.5	-94.7, -59.3	14.9, 322.7	-45.2, 40.0	2.0, 187.6	-94.3, 0.0
	Mean (SD)	20.09 (10.944)	-80.32 (6.998)	111.41 (60.680)	-3.82 (22.337)	33.77 (39.508)	-70.37 (29.980)
	95% CI of Mean	17.60, 22.58	-81.98, -78.66	92.00, 130.83	-11.39, 3.74	20.60, 46.95	-80.52, -60.22

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	15.35 (72.562)		93.23 (61.884)		19.29 (134.129)	
	95% CI of Geometric Mean	13.24, 17.80		77.70, 111.85		13.75, 27.06	
	Median	15.65	-83.43	92.86	-3.73	17.08	-84.91
	Q25, Q75	11.56, 21.88	-87.22, -78.28	72.73, 134.38	-16.40, 2.93	11.05, 37.26	-87.52, -76.02
	Min, Max	2.6, 60.4	-94.1, -48.8	15.3, 322.7	-69.7, 79.0	1.7, 187.6	-95.8, 0.0
	Mean (SD)	18.49 (11.292)	-81.69 (8.578)	107.92 (60.665)	-4.81 (24.278)	32.36 (39.524)	-71.75 (30.326)
	95% CI of Mean	15.92, 21.06	-83.73, -79.65	88.52, 127.33	-13.03, 3.41	19.17, 45.54	-82.01, -61.48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	14.54 (75.569)		93.44 (64.828)		17.42 (137.030)	
	95% CI of Geometric Mean	12.48, 16.94		77.31, 112.93		12.36, 24.55	
	Median	15.52	-84.22	97.94	-13.10	14.55	-86.71
	Q25, Q75	11.73, 20.83	-87.75, -80.69	67.83, 140.11	-23.75, 7.98	9.89, 25.66	-88.61, -79.53
	Min, Max	2.1, 52.3	-95.0, -45.6	11.2, 322.7	-62.3, 110.2	1.4, 187.6	-96.0, 0.0
	Mean (SD)	17.67 (10.895)	-83.01 (8.148)	108.48 (60.309)	-5.21 (33.355)	30.38 (39.807)	-73.25 (30.792)
	95% CI of Mean	15.19, 20.14	-84.95, -81.08	89.19, 127.77	-16.51, 6.08	17.10, 43.65	-83.68, -62.83

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	24.10 (113.098)		102.60 (66.868)		29.36 (180.661)	
	95% CI of Geometric Mean	19.61, 29.61		84.46, 124.62		19.64, 43.87	
	Median	23.85	-75.29	102.36	1.55	35.52	-69.08
	Q25, Q75	11.95, 44.16	-88.01, -52.51	69.90, 152.14	-18.15, 19.11	18.00, 70.11	-81.59, -38.10
	Min, Max	2.1, 169.3	-96.9, 52.7	19.1, 322.7	-47.6, 251.0	0.8, 187.6	-96.9, 0.0
	Mean (SD)	35.18 (32.906)	-63.58 (33.369)	121.45 (71.846)	8.67 (50.223)	49.23 (45.038)	-57.34 (32.322)
	95% CI of Mean	27.70, 42.65	-71.49, -55.68	98.46, 144.43	-8.32, 25.67	34.21, 64.25	-68.28, -46.40

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	21.83 (120.804)		95.01 (75.597)		31.58 (182.332)	
	95% CI of Geometric Mean	17.59, 27.08		76.63, 117.81		21.09, 47.28	
	Median	22.60	-78.28	111.48	0.36	38.42	-61.24
	Q25, Q75	10.79, 49.38	-88.09, -47.31	66.46, 146.20	-25.59, 23.16	25.17, 65.90	-74.98, -38.38
	Min, Max	3.2, 149.4	-97.1, 15.2	14.1, 322.7	-47.1, 89.3	1.0, 187.6	-97.6, 0.0
	Mean (SD)	32.35 (28.078)	-67.19 (26.752)	114.16 (64.919)	1.13 (32.341)	51.20 (43.384)	-55.95 (30.103)
	95% CI of Mean	25.98, 38.73	-73.53, -60.86	93.39, 134.93	-9.82, 12.08	36.73, 65.67	-66.14, -45.76

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	18.95 (161.264)		99.57 (88.871)		31.88 (205.366)	
	95% CI of Geometric Mean	14.65, 24.51		78.01, 127.09		20.77, 48.95	
	Median	22.38	-73.03	112.24	2.22	42.86	-54.61
	Q25, Q75	9.40, 47.72	-92.81, -57.27	66.64, 159.67	-25.76, 22.58	23.11, 81.08	-78.31, -30.20
	Min, Max	1.1, 121.9	-98.6, 47.1	4.4, 322.7	-77.5, 128.3	1.0, 187.6	-97.7, 3.4
	Mean (SD)	31.75 (29.489)	-67.96 (30.948)	122.71 (71.118)	4.69 (41.792)	53.26 (44.050)	-52.65 (32.096)
	95% CI of Mean	25.05, 38.44	-75.29, -60.63	99.96, 145.46	-9.45, 18.84	38.56, 67.95	-63.51, -41.78

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	74	37	37
	Missing, n (%)	6 (7.5)	4 (9.8)	2 (5.1)
	Geometric Mean (CV%)	153.17 (63.205)	166.47 (62.261)	160.40 (67.330)
	95% CI of Geometric Mean	133.91, 175.19	137.55, 201.48	130.81, 196.67
	Median	163.63	187.50	157.70
	Q25, Q75	109.84, 207.92	135.11, 246.84	109.49, 228.41
	Min, Max	29.8, 537.2	22.2, 400.0	19.5, 483.4
	Mean (SD)	179.29 (104.162)	189.50 (87.217)	187.86 (102.803)
	95% CI of Mean	155.15, 203.42	160.42, 218.58	153.58, 222.14

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 1	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	51.04 (65.773)	153.80 (64.341)	62.99 (82.423)
	95% CI of Geometric Mean	44.58, 58.44	127.72, 185.21	49.71, 79.81
	Median	53.64	158.22	61.36
	Q25, Q75	37.27, 75.59	115.82, 209.99	34.31, 94.47
	Min, Max	11.8, 215.0	19.0, 413.0	15.1, 418.3
	Mean (SD)	60.32 (36.248)	177.42 (90.128)	83.24 (77.370)
	95% CI of Mean	52.14, 68.50	148.97, 205.88	57.81, 108.68

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 2	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	30.60 (66.613)	147.95 (61.864)	38.14 (117.690)
	95% CI of Geometric Mean	26.69, 35.08	123.62, 177.08	28.07, 51.82
	Median	31.53	158.81	36.08
	Q25, Q75	21.05, 45.76	114.95, 223.41	22.27, 55.86
	Min, Max	6.9, 135.5	16.4, 360.1	4.0, 418.3
	Mean (SD)	36.32 (22.252)	168.44 (79.200)	61.32 (80.174)
	95% CI of Mean	31.30, 41.34	143.44, 193.44	34.96, 87.67

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 3	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	28.79 (67.617)	157.23 (62.085)	32.82 (126.190)
	95% CI of Geometric Mean	25.06, 33.06	131.29, 188.28	23.81, 45.24
	Median	29.10	174.71	28.67
	Q25, Q75	22.31, 43.66	117.89, 233.04	16.78, 47.24
	Min, Max	4.1, 110.8	14.7, 338.1	5.5, 418.3
	Mean (SD)	34.13 (20.473)	177.97 (78.762)	56.93 (82.022)
	95% CI of Mean	29.51, 38.75	153.11, 202.84	29.96, 83.89

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 4	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	25.84 (72.101)	151.71 (61.550)	30.60 (134.213)
	95% CI of Geometric Mean	22.33, 29.91	126.86, 181.44	21.92, 42.72
	Median	25.83	161.57	31.06
	Q25, Q75	17.50, 39.82	113.16, 223.80	17.52, 43.25
	Min, Max	4.0, 96.9	16.9, 348.9	4.2, 418.3
	Mean (SD)	31.23 (19.561)	172.31 (78.992)	54.85 (81.534)
	95% CI of Mean	26.82, 35.65	147.38, 197.25	28.05, 81.66

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 5	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	25.29 (78.712)	155.34 (66.745)	29.20 (136.689)
	95% CI of Geometric Mean	21.62, 29.58	128.25, 188.15	20.83, 40.92
	Median	27.36	154.01	26.71
	Q25, Q75	20.19, 38.29	120.97, 249.37	15.84, 44.44
	Min, Max	3.1, 97.5	13.6, 397.2	3.7, 418.3
	Mean (SD)	31.12 (19.795)	178.91 (85.994)	53.49 (81.591)
	95% CI of Mean	26.66, 35.59	151.77, 206.06	26.67, 80.31

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	40.45 (125.221)	165.14 (66.956)	47.12 (181.201)
	95% CI of Geometric Mean	32.49, 50.36	136.27, 200.12	31.69, 70.05
	Median	42.55	170.90	54.91
	Q25, Q75	19.86, 77.79	111.82, 245.40	26.36, 98.41
	Min, Max	2.4, 331.2	32.1, 528.2	1.9, 418.3
	Mean (SD)	61.99 (61.203)	194.97 (113.841)	83.00 (88.703)
	95% CI of Mean	48.19, 75.80	159.03, 230.91	53.84, 112.16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	36.30 (131.048)	155.64 (69.637)	52.02 (196.170)
	95% CI of Geometric Mean	28.97, 45.48	127.62, 189.81	34.41, 78.62
	Median	36.21	169.58	59.79
	Q25, Q75	16.33, 82.64	115.41, 229.02	37.05, 121.34
	Min, Max	4.1, 331.2	15.5, 522.9	2.4, 418.3
	Mean (SD)	57.31 (57.949)	182.13 (95.835)	90.06 (86.802)
	95% CI of Mean	44.24, 70.38	151.87, 212.38	61.52, 118.60

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.13.2 Descriptive Statistics of CEMA in 24-hour Urine Collection - FAS****Parameter (units): CEMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	32.85 (167.694)	158.32 (84.620)	50.67 (205.794)
	95% CI of Geometric Mean	25.31, 42.65	125.54, 199.65	33.19, 77.34
	Median	37.89	172.02	66.18
	Q25, Q75	11.86, 83.66	117.11, 259.68	33.44, 111.84
	Min, Max	2.3, 331.2	5.3, 434.8	2.5, 418.3
	Mean (SD)	57.25 (58.951)	188.85 (95.217)	88.62 (86.128)
	95% CI of Mean	43.95, 70.54	158.79, 218.91	60.31, 116.94

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set****Parameter (units): HEMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		30		21	
	Missing, n (%)	8 (10.7)		5 (14.3)		3 (12.5)	
	Geometric Mean (CV%)	3702.58 (105.462)		3520.78 (97.271)		3289.73 (92.480)	
	95% CI of Geometric Mean	2998.48, 4572.00		2596.02, 4774.95		2300.10, 4705.13	
	Median	3993.06		3327.05		3295.77	
	Q25, Q75	1961.62, 7303.61		2267.61, 6053.51		2147.40, 6056.78	
	Min, Max	736.9, 21768.7		778.4, 18109.2		409.3, 13621.7	
	Mean (SD)	5298.45 (4743.433)		4835.98 (4295.786)		4259.29 (3109.885)	
	95% CI of Mean	4141.43, 6455.46		3231.90, 6440.06		2843.68, 5674.90	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set****Parameter (units): HEMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	2098.45 (88.983)		3307.58 (101.490)		2118.79 (65.945)	
	95% CI of Geometric Mean	1755.96, 2507.74		2466.05, 4436.27		1623.24, 2765.64	
	Median	2067.67	-45.39	3275.82	-2.05	2377.15	-47.58
	Q25, Q75	1223.70, 3371.68	-58.00, -24.06	1932.79, 5886.52	-18.79, 22.77	1476.19, 3109.54	-51.56, -31.86
	Min, Max	322.0, 16751.3	-75.7, 26.6	602.7, 15742.6	-61.7, 84.8	743.8, 5329.9	-65.3, 81.7
	Mean (SD)	2866.10 (2854.331)	-39.50 (23.877)	4562.14 (3886.748)	0.55 (32.798)	2472.11 (1295.082)	-31.10 (36.347)
	95% CI of Mean	2200.13, 3532.07	-45.33, -33.68	3205.98, 5918.29	-11.70, 12.80	1897.89, 3046.32	-47.65, -14.55

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set****Parameter (units): HEMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	1154.29 (85.457)		2869.72 (100.831)		1222.58 (56.560)	
	95% CI of Geometric Mean	971.15, 1371.98		2142.53, 3843.73		967.90, 1544.27	
	Median	1111.25	-68.98	3238.63	-19.25	1398.69	-65.65
	Q25, Q75	660.86, 1786.09	-74.73, -57.36	1758.39, 5120.85	-34.03, 11.62	865.30, 1666.67	-72.75, -56.99
	Min, Max	247.6, 9901.6	-91.4, -19.0	492.1, 10084.0	-67.7, 138.8	454.4, 3712.1	-79.3, 11.0
	Mean (SD)	1548.62 (1465.615)	-64.25 (16.422)	3810.87 (2602.061)	-7.91 (42.495)	1388.04 (731.355)	-59.49 (22.464)
	95% CI of Mean	1206.66, 1890.57	-68.26, -60.24	2902.96, 4718.77	-23.78, 7.96	1063.78, 1712.31	-69.72, -49.26

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set**

Parameter (units): HEMA (pg/mg creat)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	1095.42 (77.409)		3224.45 (105.179)		1140.89 (64.477)	
	95% CI of Geometric Mean	933.57, 1285.32		2386.00, 4357.54		878.43, 1481.76	
	Median	993.01	-71.10	3688.37	-8.92	1215.01	-71.43
	Q25, Q75	624.11, 1699.05	-79.42, -56.92	1898.15, 5330.19	-24.75, 25.88	707.20, 1730.22	-77.61, -45.13
	Min, Max	315.7, 5333.3	-91.9, 17.5	502.3, 20048.6	-52.4, 68.4	428.1, 2929.7	-86.8, 120.4
	Mean (SD)	1392.33 (1050.148)	-66.49 (17.978)	4515.72 (4098.254)	-2.43 (30.062)	1336.29 (757.700)	-55.36 (45.665)
	95% CI of Mean	1147.31, 1637.35	-70.88, -62.10	3085.77, 5945.68	-13.66, 8.80	1000.34, 1672.24	-76.15, -34.57

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set****Parameter (units): HEMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	1053.94 (82.168)		2859.12 (103.663)		1008.95 (82.620)	
	95% CI of Geometric Mean	891.32, 1246.23		2122.19, 3851.95		732.77, 1389.21	
	Median	975.66	-68.31	3176.95	-16.39	986.95	-74.25
	Q25, Q75	594.47, 1701.49	-80.55, -54.68	1681.42, 4486.90	-33.89, 0.71	522.73, 1963.09	-80.14, -49.56
	Min, Max	282.4, 4351.1	-93.1, -6.6	356.4, 16039.6	-63.3, 139.5	349.7, 3507.5	-91.7, 2.9
	Mean (SD)	1371.43 (1073.738)	-66.43 (16.772)	3937.07 (3407.977)	-8.23 (41.486)	1283.87 (899.328)	-61.94 (26.517)
	95% CI of Mean	1120.90, 1621.96	-70.53, -62.34	2747.97, 5126.18	-23.72, 7.27	885.12, 1682.61	-74.01, -49.86

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set****Parameter (units): HEMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	1145.34 (94.086)		2903.31 (101.813)		1075.28 (90.757)	
	95% CI of Geometric Mean	951.15, 1379.18		2163.19, 3896.66		762.54, 1516.30	
	Median	967.96	-65.84	3647.47	-10.86	1137.86	-72.56
	Q25, Q75	650.50, 1935.48	-79.11, -54.06	1494.87, 4771.08	-37.04, 8.73	605.04, 1909.26	-77.83, -51.75
	Min, Max	200.0, 6806.3	-93.3, 9.1	489.6, 17316.7	-84.2, 87.1	249.2, 4087.6	-91.1, -10.7
	Mean (SD)	1590.21 (1450.465)	-62.69 (20.848)	3953.27 (3303.599)	-7.74 (39.957)	1411.45 (1071.443)	-62.03 (23.280)
	95% CI of Mean	1251.79, 1928.64	-67.78, -57.60	2800.59, 5105.96	-22.66, 7.19	936.40, 1886.51	-72.63, -51.43

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set****Parameter (units): HEMA (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		29		12	
	Missing, n (%)	3 (7.5)		5 (14.7)		1 (7.7)	
	Geometric Mean (CV%)	3845.71 (99.413)		3422.03 (99.090)		3975.82 (69.941)	
	95% CI of Geometric Mean	2916.97, 5070.14		2498.35, 4687.20		2662.55, 5936.84	
	Median	3993.06		3184.93		4168.03	
	Q25, Q75	2284.91, 7774.44		2267.61, 6053.51		2653.02, 6170.18	
	Min, Max	845.8, 21522.5		778.4, 18109.2		1325.4, 13621.7	
	Mean (SD)	5322.22 (4532.157)		4768.62 (4379.922)		4779.39 (3277.168)	
	95% CI of Mean	3811.11, 6833.32		3102.58, 6434.66		2697.17, 6861.61	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set****Parameter (units): HEMA (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	37	33	29	13	12
	Missing, n (%)	0	3 (7.5)	1 (2.9)	5 (14.7)	0	1 (7.7)
	Geometric Mean (CV%)	1900.15 (101.471)		3926.61 (91.013)		2765.82 (65.356)	
	95% CI of Geometric Mean	1451.87, 2486.82		2981.24, 5171.77		1928.90, 3965.88	
	Median	1726.39	-48.73	4624.45	21.22	3261.85	-17.56
	Q25, Q75	1133.81, 3907.62	-69.15, -24.40	3441.21, 6166.42	-9.61, 46.92	2112.55, 3838.71	-60.34, 4.67
	Min, Max	194.2, 10041.0	-94.3, 122.6	767.7, 12075.2	-61.9, 169.1	887.9, 8066.7	-84.0, 275.6
	Mean (SD)	2634.87 (2291.596)	-36.09 (49.853)	4985.79 (3077.057)	28.02 (51.939)	3212.46 (1811.087)	-3.02 (97.105)
	95% CI of Mean	1901.98, 3367.76	-52.72, -19.46	3894.71, 6076.88	8.26, 47.79	2118.02, 4306.89	-64.72, 58.68

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set**

Parameter (units): HEMA (pg/mg creat)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	35		30		11	
	Missing, n (%)	4 (10.3)		5 (14.3)		1 (8.3)	
	Geometric Mean (CV%)	3875.21 (102.865)		3485.91 (97.758)		3153.63 (117.269)	
	95% CI of Geometric Mean	2894.34, 5188.48		2567.46, 4732.92		1688.27, 5890.87	
	Median	3993.06		3313.40		3761.06	
	Q25, Q75	1991.40, 7968.04		2267.61, 6053.51		1953.73, 6056.78	
	Min, Max	845.8, 21522.5		778.4, 18109.2		409.3, 13621.7	
	Mean (SD)	5416.83 (4617.035)		4808.34 (4309.240)		4365.03 (3597.906)	
	95% CI of Mean	3830.82, 7002.85		3199.24, 6417.44		1947.92, 6782.14	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set****Parameter (units): HEMA (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	35	34	30	11	11
	Missing, n (%)	0	4 (10.3)	1 (2.9)	5 (14.3)	1 (8.3)	1 (8.3)
	Geometric Mean (CV%)	1747.26 (94.305)		3555.70 (103.425)		1910.75 (106.628)	
	95% CI of Geometric Mean	1349.16, 2262.83		2640.51, 4788.10		1064.03, 3431.26	
	Median	1702.90	-56.66	4274.41	6.20	2281.69	-39.33
	Q25, Q75	952.98, 3107.97	-73.21, -31.36	2598.58, 6072.80	-24.23, 53.65	1708.33, 3058.57	-63.44, 35.73
	Min, Max	386.2, 10560.5	-95.9, 60.2	511.8, 21140.9	-61.9, 113.3	297.2, 4818.2	-89.3, 263.5
	Mean (SD)	2389.72 (2128.506)	-47.04 (36.025)	4786.05 (3853.506)	14.52 (49.368)	2457.81 (1458.413)	-7.56 (99.829)
	95% CI of Mean	1699.73, 3079.71	-59.42, -34.66	3441.49, 6130.61	-3.92, 32.96	1478.03, 3437.59	-74.63, 59.51

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set****Parameter (units): HEMA (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	43		29		9	
	Missing, n (%)	4 (8.5)		3 (9.4)		0	
	Geometric Mean (CV%)	3848.11 (99.458)		3307.99 (91.615)		2906.82 (132.561)	
	95% CI of Geometric Mean	2981.31, 4966.93		2458.13, 4451.69		1340.36, 6303.95	
	Median	3993.06		3184.93		3761.06	
	Q25, Q75	2113.82, 7774.44		2267.61, 5960.37		1953.73, 4585.56	
	Min, Max	845.8, 21522.5		778.4, 18109.2		409.3, 13621.7	
	Mean (SD)	5324.41 (4483.917)		4424.96 (3829.589)		4270.67 (3945.647)	
	95% CI of Mean	3944.46, 6704.36		2968.26, 5881.66		1237.77, 7303.57	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set****Parameter (units): HEMA (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	43	32	29	9	9
	Missing, n (%)	0	4 (8.5)	0	3 (9.4)	0	
	Geometric Mean (CV%)	1481.32 (84.628)		3265.62 (131.543)		1565.88 (84.107)	
	95% CI of Geometric Mean	1193.81, 1838.07		2275.30, 4686.97		892.46, 2747.43	
	Median	1387.93	-55.49	3895.32	8.19	1725.24	-50.76
	Q25, Q75	922.48, 2373.37	-76.24, -35.80	2072.27, 5868.97	-17.62, 23.04	1232.38, 2395.48	-73.55, 22.61
	Min, Max	400.0, 13759.5	-96.0, 22.5	154.9, 20141.3	-65.3, 192.2	360.2, 4259.9	-91.0, 221.4
	Mean (SD)	1993.85 (2095.321)	-53.06 (28.286)	4896.04 (4603.230)	13.40 (48.588)	1914.86 (1178.669)	-9.84 (98.260)
	95% CI of Mean	1378.64, 2609.06	-61.77, -44.35	3236.39, 6555.69	-5.08, 31.89	1008.85, 2820.87	-85.37, 65.70

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set****Parameter (units): HEMA (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	70	31	22
	Missing, n (%)	5 (6.7)	4 (11.4)	2 (8.3)
	Geometric Mean (CV%)	6143.24 (92.373)	5637.72 (87.756)	5258.31 (78.840)
	95% CI of Geometric Mean	5094.01, 7408.58	4272.92, 7438.44	3863.39, 7156.89
	Median	6059.30	6772.85	5425.08
	Q25, Q75	3290.00, 10292.00	3331.26, 8773.95	4260.49, 7788.24
	Min, Max	1524.4, 44074.9	1558.2, 28600.8	611.0, 17778.4
	Mean (SD)	8386.00 (7516.430)	7411.55 (6113.769)	6364.07 (3899.952)
	95% CI of Mean	6593.77, 10178.23	5168.99, 9654.10	4634.93, 8093.22

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set****Parameter (units): HEMA (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	3438.08 (74.974)	5376.62 (90.808)	3332.13 (60.820)
	95% CI of Geometric Mean	2945.22, 4013.42	4119.27, 7017.77	2614.33, 4247.01
	Median	3312.24	6411.96	3088.76
	Q25, Q75	2336.33, 5310.58	3199.15, 8226.96	2299.28, 5059.36
	Min, Max	670.2, 22127.8	1226.0, 23452.5	978.4, 8724.8
	Mean (SD)	4362.92 (3722.299)	7096.23 (5592.913)	3850.14 (2101.522)
	95% CI of Mean	3500.53, 5225.31	5174.99, 9017.47	2941.37, 4758.91

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set****Parameter (units): HEMA (ng)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	1912.85 (76.071)	4739.07 (86.734)	1946.43 (49.433)
	95% CI of Geometric Mean	1635.65, 2237.02	3664.05, 6129.49	1590.11, 2382.59
	Median	1842.34	6229.60	2008.24
	Q25, Q75	1247.62, 3022.44	2828.25, 8359.74	1334.87, 2471.74
	Min, Max	368.2, 20551.1	1076.9, 16344.0	812.9, 4161.8
	Mean (SD)	2480.92 (2578.270)	5954.66 (3627.121)	2158.80 (1013.029)
	95% CI of Mean	1883.58, 3078.26	4708.69, 7200.62	1720.73, 2596.87

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set**

Parameter (units): HEMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	1799.04 (66.319)	5307.49 (91.746)	1722.83 (55.423)
	95% CI of Geometric Mean	1564.20, 2069.15	4057.93, 6941.83	1377.35, 2154.97
	Median	1809.50	6829.05	1617.84
	Q25, Q75	1143.00, 2622.83	2904.60, 8509.20	1105.14, 2413.68
	Min, Max	450.1, 7924.8	1131.4, 27670.5	900.9, 7147.1
	Mean (SD)	2162.33 (1434.686)	6983.52 (5453.913)	1997.40 (1358.213)
	95% CI of Mean	1829.94, 2494.73	5110.03, 8857.01	1410.06, 2584.74

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set**

Parameter (units): HEMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	1747.49 (68.168)	4599.54 (88.312)	1566.97 (75.224)
	95% CI of Geometric Mean	1514.45, 2016.39	3543.53, 5970.25	1172.99, 2093.26
	Median	1673.53	4627.68	2101.50
	Q25, Q75	1164.94, 2635.47	2872.80, 6888.36	814.51, 2653.98
	Min, Max	593.5, 7213.7	735.8, 22032.0	510.7, 6039.0
	Mean (SD)	2124.38 (1446.759)	6031.24 (4890.559)	1927.65 (1290.134)
	95% CI of Mean	1789.19, 2459.58	4351.27, 7711.21	1369.75, 2485.56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set**

Parameter (units): HEMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	1960.33 (83.879)	4768.46 (91.261)	1784.38 (87.798)
	95% CI of Geometric Mean	1655.35, 2321.50	3649.69, 6230.19	1286.82, 2474.33
	Median	1841.72	5992.74	1902.64
	Q25, Q75	1127.92, 3488.40	2585.24, 7801.55	1213.87, 3087.90
	Min, Max	426.1, 8931.0	1079.8, 23920.5	374.1, 10438.4
	Mean (SD)	2555.37 (2002.147)	6198.28 (4539.285)	2347.09 (2075.745)
	95% CI of Mean	2091.51, 3019.24	4638.98, 7757.59	1449.47, 3244.71

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set**

Parameter (units): HEMA (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	38	30	12
	Missing, n (%)	2 (5.0)	4 (11.8)	1 (7.7)
	Geometric Mean (CV%)	6401.05 (86.297)	5667.91 (87.436)	6228.63 (59.702)
	95% CI of Geometric Mean	5009.03, 8179.91	4277.77, 7509.80	4385.68, 8846.01
	Median	6924.08	6066.52	6367.74
	Q25, Q75	3413.34, 10292.00	3751.93, 8773.95	4513.00, 9372.24
	Min, Max	1872.8, 44074.9	1558.2, 28600.8	2462.4, 14257.6
	Mean (SD)	8490.25 (7651.743)	7448.87 (6178.898)	7120.18 (3773.905)
	95% CI of Mean	5975.18, 11005.32	5141.63, 9756.11	4722.35, 9518.01

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set**

Parameter (units): HEMA (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Day 30	n	40	34	13
	Geometric Mean (CV%)	3078.69 (95.950)	6670.66 (79.715)	4542.96 (65.793)
	95% CI of Geometric Mean	2377.70, 3986.34	5222.63, 8520.17	3161.87, 6527.29
	Median	3424.83	7413.18	4065.04
	Q25, Q75	1888.53, 5028.20	4815.36, 12060.09	3419.38, 6009.20
	Min, Max	311.6, 14984.2	1486.7, 17802.5	1592.3, 18312.1
	Mean (SD)	4104.03 (3274.223)	8159.59 (4661.720)	5487.40 (4271.264)
	95% CI of Mean	3056.88, 5151.18	6533.03, 9786.14	2906.29, 8068.50

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set**

Parameter (units): HEMA (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	37	31	12
	Missing, n (%)	2 (5.1)	4 (11.4)	0
	Geometric Mean (CV%)	6430.17 (87.528)	5731.90 (85.919)	5090.11 (105.432)
	95% CI of Geometric Mean	5000.54, 8268.52	4363.67, 7529.13	2938.78, 8816.33
	Median	6901.56	6772.85	5276.83
	Q25, Q75	3461.04, 10713.30	3751.93, 8773.95	3566.09, 9372.24
	Min, Max	2029.9, 44074.9	1558.2, 28600.8	611.0, 14257.6
	Mean (SD)	8579.47 (7765.778)	7467.53 (6075.931)	6591.47 (4210.127)
	95% CI of Mean	5990.22, 11168.71	5238.85, 9696.20	3916.48, 9266.47

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set**

Parameter (units): HEMA (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Day 60	n	39	35	12
	Geometric Mean (CV%)	2838.16 (88.315)	5943.77 (102.770)	3108.20 (91.915)
	95% CI of Geometric Mean	2218.89, 3630.25	4440.17, 7956.54	1890.48, 5110.29
	Median	3067.76	7890.61	3280.85
	Q25, Q75	1643.81, 4826.04	4086.92, 10293.40	2388.38, 5265.64
	Min, Max	461.2, 11398.2	600.9, 33024.6	460.5, 8670.7
	Mean (SD)	3652.84 (2551.593)	7913.89 (5975.562)	3897.67 (2488.097)
	95% CI of Mean	2825.71, 4479.98	5861.20, 9966.57	2316.80, 5478.53

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set**

Parameter (units): HEMA (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	45	29	9
	Missing, n (%)	2 (4.3)	3 (9.4)	0
	Geometric Mean (CV%)	6300.58 (89.731)	5412.16 (82.368)	4714.57 (128.095)
	95% CI of Geometric Mean	5001.54, 7937.01	4116.14, 7116.26	2210.41, 10055.63
	Median	6901.56	5360.19	4928.30
	Q25, Q75	3290.00, 10713.30	3751.93, 8070.37	2871.68, 9246.72
	Min, Max	1872.8, 44074.9	1558.2, 28600.8	611.0, 14257.6
	Mean (SD)	8481.94 (7589.391)	6933.16 (5552.556)	6561.60 (4780.110)
	95% CI of Mean	6201.83, 10762.05	4821.07, 9045.24	2887.28, 10235.92

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.1 Descriptive Statistics of HEMA in 24-hour Urine Collection - PP Set**

Parameter (units): HEMA (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Day 90	n	47	32	9
	Geometric Mean (CV%)	2485.52 (77.870)	5421.96 (116.668)	2680.42 (112.781)
	95% CI of Geometric Mean	2030.62, 3042.33	3881.70, 7573.38	1335.95, 5377.93
	Median	2483.74	6216.85	2893.40
	Q25, Q75	1603.47, 3639.35	3080.22, 9919.98	2113.44, 4375.68
	Min, Max	643.3, 25222.2	389.0, 28916.1	414.7, 8701.2
	Mean (SD)	3266.99 (3629.802)	7663.72 (6351.873)	3585.09 (2576.207)
	95% CI of Mean	2201.23, 4332.74	5373.62, 9953.82	1604.84, 5565.34

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		36		36	
	Missing, n (%)	9 (11.3)		5 (12.2)		3 (7.7)	
	Geometric Mean (CV%)	3796.11 (103.851)		3740.41 (94.380)		3518.83 (98.738)	
	95% CI of Geometric Mean	3100.34, 4648.00		2855.23, 4900.01		2661.81, 4651.78	
	Median	4245.61		3441.36		3565.31	
	Q25, Q75	1991.40, 7774.44		2347.39, 6501.05		2267.44, 6170.18	
	Min, Max	736.9, 21768.7		778.4, 18109.2		332.4, 13621.7	
	Mean (SD)	5368.40 (4668.004)		5058.67 (4278.201)		4628.89 (3310.331)	
	95% CI of Mean	4263.50, 6473.30		3611.13, 6506.21		3508.83, 5748.95	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	2125.13 (88.606)		3517.69 (96.896)		2308.95 (87.497)	
	95% CI of Geometric Mean	1787.92, 2525.94		2711.68, 4563.27		1795.72, 2968.87	
	Median	2081.30	-46.76	3622.62	-4.43	2672.73	-36.41
	Q25, Q75	1223.70, 3514.85	-58.00, -28.69	2198.04, 6073.96	-18.68, 18.13	1506.11, 3745.90	-51.92, -4.90
	Min, Max	322.0, 16751.3	-75.7, 26.6	602.7, 15742.6	-61.7, 84.8	192.1, 12061.5	-65.3, 81.7
	Mean (SD)	2883.64 (2801.215)	-40.23 (23.517)	4733.38 (3788.359)	0.86 (32.543)	2936.46 (2178.320)	-29.79 (31.583)
	95% CI of Mean	2247.84, 3519.44	-45.80, -34.66	3521.79, 5944.96	-10.15, 11.88	2210.17, 3662.76	-40.48, -19.10

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	1183.26 (85.231)		3124.75 (100.243)		1469.73 (90.916)	
	95% CI of Geometric Mean	1000.55, 1399.34		2393.18, 4079.95		1134.61, 1903.84	
	Median	1138.12	-68.39	3339.41	-18.30	1439.39	-59.77
	Q25, Q75	691.24, 1787.33	-74.27, -59.60	1942.32, 5838.35	-31.09, 11.37	954.55, 1818.18	-72.94, -45.31
	Min, Max	247.6, 9901.6	-91.4, -19.0	492.1, 13881.6	-67.7, 138.8	180.0, 12061.5	-82.2, 11.0
	Mean (SD)	1578.40 (1450.476)	-64.43 (15.992)	4160.31 (2961.428)	-5.19 (44.140)	2030.01 (2196.796)	-51.99 (28.124)
	95% CI of Mean	1249.18, 1907.62	-68.22, -60.64	3213.20, 5107.43	-20.13, 9.75	1297.56, 2762.47	-61.51, -42.47

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	1115.59 (76.829)		3518.17 (102.343)		1444.87 (92.749)	
	95% CI of Geometric Mean	955.79, 1302.10		2683.74, 4612.03		1111.08, 1878.93	
	Median	1001.80	-71.96	3798.30	-5.16	1289.99	-62.29
	Q25, Q75	660.13, 1745.22	-79.27, -57.16	2338.06, 6206.13	-19.89, 22.00	1046.30, 2167.18	-77.49, -26.09
	Min, Max	315.7, 5333.3	-91.9, 17.5	502.3, 20048.6	-52.4, 129.1	263.4, 12061.5	-86.8, 120.4
	Mean (SD)	1410.83 (1041.031)	-66.85 (17.533)	4827.53 (4070.119)	1.52 (35.318)	2019.38 (2199.911)	-47.73 (41.294)
	95% CI of Mean	1174.54, 1647.12	-71.01, -62.70	3525.83, 6129.22	-10.44, 13.47	1285.89, 2752.88	-61.71, -33.76

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	1083.14 (82.136)		3128.14 (102.156)		1386.72 (105.765)	
	95% CI of Geometric Mean	920.24, 1274.87		2387.06, 4099.28		1038.78, 1851.21	
	Median	976.11	-68.31	3342.54	-15.90	1452.05	-57.92
	Q25, Q75	621.32, 1779.24	-80.46, -55.80	2288.52, 5335.07	-32.83, 2.23	642.28, 2420.63	-76.85, -26.62
	Min, Max	282.4, 4351.1	-93.1, -6.6	356.4, 16039.6	-63.3, 186.7	310.7, 12061.5	-91.7, 2.9
	Mean (SD)	1403.60 (1071.301)	-66.57 (16.308)	4256.56 (3464.385)	-3.74 (50.293)	2034.27 (2238.256)	-50.65 (31.183)
	95% CI of Mean	1160.44, 1646.77	-70.44, -62.71	3148.59, 5364.53	-20.76, 13.28	1287.99, 2780.54	-61.21, -40.09

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	1185.75 (94.065)		3197.33 (102.445)		1419.25 (110.142)	
	95% CI of Geometric Mean	989.72, 1420.60		2438.53, 4192.23		1054.38, 1910.38	
	Median	1018.16	-65.39	3709.46	-8.95	1333.33	-56.72
	Q25, Q75	666.06, 2073.39	-78.63, -54.06	1934.95, 5036.21	-34.02, 10.53	730.63, 2722.60	-77.29, -30.28
	Min, Max	200.0, 6806.3	-93.3, 9.1	489.6, 17316.7	-84.2, 122.5	249.2, 12061.5	-91.1, 1.0
	Mean (SD)	1635.79 (1445.767)	-62.59 (20.296)	4375.46 (3663.651)	-3.56 (42.813)	2105.84 (2273.196)	-50.84 (30.528)
	95% CI of Mean	1307.64, 1963.95	-67.40, -57.78	3203.77, 5547.16	-18.05, 10.93	1347.91, 2863.76	-61.18, -40.51

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	2137.12 (103.860)		4166.88 (89.187)		2540.06 (100.472)	
	95% CI of Geometric Mean	1759.98, 2595.08		3262.54, 5321.90		1922.55, 3355.90	
	Median	1818.40	-46.56	4670.98	17.50	2889.69	-13.47
	Q25, Q75	1266.09, 3913.58	-62.78, -1.27	3326.72, 6402.20	-8.10, 41.84	1906.25, 3740.57	-51.07, 0.38
	Min, Max	194.2, 19405.9	-94.3, 125.8	767.7, 19250.0	-61.9, 169.1	229.7, 12061.5	-84.0, 275.6
	Mean (SD)	3125.03 (3386.653)	-27.00 (50.964)	5324.29 (3667.023)	23.32 (48.274)	3379.92 (2645.725)	-14.72 (59.925)
	95% CI of Mean	2356.35, 3893.71	-39.07, -14.93	4151.51, 6497.06	6.99, 39.66	2497.78, 4262.05	-35.00, 5.56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	1907.25 (101.081)		3881.02 (101.500)		2439.83 (88.744)	
	95% CI of Geometric Mean	1576.53, 2307.35		2965.27, 5079.58		1892.35, 3145.69	
	Median	1867.47	-55.28	4505.58	6.20	2805.97	-22.66
	Q25, Q75	1001.22, 3261.42	-69.14, -20.47	2984.85, 6209.87	-20.77, 52.68	2122.64, 3369.57	-59.84, 6.44
	Min, Max	212.2, 22336.1	-95.9, 292.0	511.8, 21140.9	-61.9, 113.3	297.2, 12061.5	-89.3, 263.5
	Mean (SD)	2754.42 (3097.566)	-36.61 (55.460)	5213.05 (4244.714)	16.33 (47.830)	3075.94 (2144.008)	-15.26 (63.248)
	95% CI of Mean	2051.36, 3457.49	-49.74, -23.48	3855.52, 6570.58	0.14, 32.52	2361.09, 3790.79	-36.66, 6.15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	1621.04 (112.955)		3605.57 (121.971)		2229.64 (97.088)	
	95% CI of Geometric Mean	1319.48, 1991.52		2656.92, 4892.93		1699.18, 2925.71	
	Median	1561.60	-54.96	3910.95	1.13	2420.63	-27.76
	Q25, Q75	937.01, 2817.26	-74.88, -26.98	2341.04, 6032.83	-19.83, 30.38	1411.19, 3663.06	-58.98, 0.00
	Min, Max	167.9, 13759.5	-96.0, 224.0	154.9, 20141.3	-65.3, 192.2	213.2, 12061.5	-91.0, 221.4
	Mean (SD)	2435.64 (2586.915)	-41.32 (53.176)	5231.20 (4740.953)	10.46 (47.020)	2941.76 (2270.833)	-23.52 (54.017)
	95% CI of Mean	1848.48, 3022.80	-53.91, -28.73	3714.96, 6747.43	-5.45, 26.38	2184.62, 3698.90	-41.80, -5.24

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	74	37	37
	Missing, n (%)	6 (7.5)	4 (9.8)	2 (5.1)
	Geometric Mean (CV%)	6299.43 (91.478)	6017.12 (85.555)	5734.01 (84.424)
	95% CI of Geometric Mean	5258.26, 7546.74	4699.74, 7703.77	4489.94, 7322.80
	Median	6519.16	6772.85	5625.36
	Q25, Q75	3391.20, 11719.76	4242.10, 9769.65	4414.88, 9398.86
	Min, Max	1524.4, 44074.9	1558.2, 28600.8	611.0, 18053.0
	Mean (SD)	8517.80 (7386.694)	7797.04 (6039.050)	7116.49 (4384.952)
	95% CI of Mean	6806.43, 10229.16	5783.52, 9810.56	5654.47, 8578.51

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 1	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	3473.38 (75.141)	5697.20 (86.792)	3769.37 (79.334)
	95% CI of Geometric Mean	2987.03, 4038.92	4497.21, 7217.37	2995.90, 4742.54
	Median	3422.56	6494.25	4082.04
	Q25, Q75	2336.33, 5408.24	3666.94, 8344.96	2303.25, 6531.25
	Min, Max	670.2, 22127.8	1226.0, 23452.5	584.5, 18053.0
	Mean (SD)	4393.27 (3659.256)	7342.19 (5377.494)	4734.63 (3464.510)
	95% CI of Mean	3568.23, 5218.31	5644.84, 9039.54	3595.87, 5873.39

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 2	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	1953.45 (75.801)	5134.77 (86.573)	2388.78 (80.950)
	95% CI of Geometric Mean	1678.13, 2273.94	4055.10, 6501.91	1891.63, 3016.59
	Median	1883.17	6266.58	2125.07
	Q25, Q75	1294.44, 3051.28	3424.80, 8955.68	1601.95, 3577.00
	Min, Max	368.2, 20551.1	1076.9, 16344.0	478.2, 18053.0
	Mean (SD)	2518.90 (2535.761)	6445.88 (3886.459)	3199.99 (3347.951)
	95% CI of Mean	1947.17, 3090.63	5219.15, 7672.60	2099.55, 4300.44

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 3	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	1829.00 (65.575)	5737.08 (89.051)	2252.01 (85.062)
	95% CI of Geometric Mean	1598.28, 2093.03	4507.58, 7301.93	1767.04, 2870.09
	Median	1834.76	6936.33	2031.86
	Q25, Q75	1182.02, 2664.52	3117.64, 8969.54	1237.83, 2952.86
	Min, Max	450.1, 7924.8	1131.4, 27670.5	712.9, 18053.0
	Mean (SD)	2186.77 (1414.007)	7404.77 (5340.396)	3125.80 (3450.760)
	95% CI of Mean	1867.96, 2505.59	5719.13, 9090.41	1991.56, 4260.04

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 4	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	1787.18 (68.227)	5046.54 (88.996)	2189.61 (100.340)
	95% CI of Geometric Mean	1554.65, 2054.49	3965.48, 6422.31	1664.29, 2880.74
	Median	1701.12	5032.00	2312.64
	Q25, Q75	1203.33, 2674.08	3389.95, 8948.92	1024.86, 3325.88
	Min, Max	593.5, 7213.7	735.8, 22032.0	510.7, 18053.0
	Mean (SD)	2167.28 (1441.338)	6579.46 (4967.041)	3165.43 (3448.551)
	95% CI of Mean	1842.30, 2492.25	5011.66, 8147.26	2031.91, 4298.94

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 5	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	2025.40 (83.871)	5266.82 (91.859)	2381.45 (103.350)
	95% CI of Geometric Mean	1718.09, 2387.67	4114.57, 6741.74	1799.52, 3151.56
	Median	1983.44	6133.40	2267.97
	Q25, Q75	1282.20, 3671.37	3162.60, 8209.02	1484.20, 4069.44
	Min, Max	426.1, 8931.0	1079.8, 23920.5	374.1, 18053.0
	Mean (SD)	2627.41 (1996.954)	6833.66 (4807.330)	3450.44 (3610.178)
	95% CI of Mean	2177.16, 3077.66	5316.27, 8351.05	2263.79, 4637.08

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	3491.28 (95.394)	6704.22 (79.447)	4115.86 (91.013)
	95% CI of Geometric Mean	2912.17, 4185.56	5376.02, 8360.57	3188.41, 5313.09
	Median	3470.71	7384.80	4147.09
	Q25, Q75	2301.06, 5539.10	4352.04, 12060.09	3179.00, 5396.60
	Min, Max	311.6, 32121.0	1486.7, 20628.3	575.4, 22695.3
	Mean (SD)	4862.97 (4934.908)	8256.04 (4953.667)	5490.26 (4842.561)
	95% CI of Mean	3750.31, 5975.62	6692.46, 9819.61	3898.55, 7081.98

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	3086.79 (90.998)	6305.40 (100.078)	4069.34 (81.468)
	95% CI of Geometric Mean	2590.92, 3677.56	4847.54, 8201.68	3218.67, 5144.84
	Median	3157.58	8023.27	4352.68
	Q25, Q75	1888.50, 5128.76	4615.80, 10446.54	2678.01, 6181.84
	Min, Max	461.2, 32329.4	600.9, 33024.6	460.5, 18053.0
	Mean (SD)	4217.08 (4312.866)	8296.71 (5975.023)	5062.78 (3443.946)
	95% CI of Mean	3244.68, 5189.49	6410.75, 10182.66	3930.78, 6194.78

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.14.2 Descriptive Statistics of HEMA in 24-hour Urine Collection - FAS****Parameter (units): HEMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	2735.76 (96.387)	5702.70 (105.724)	3596.67 (94.455)
	95% CI of Geometric Mean	2278.81, 3284.34	4338.48, 7495.89	2766.34, 4676.24
	Median	2952.19	6642.58	3778.38
	Q25, Q75	1668.03, 4389.60	3392.93, 9252.36	2232.82, 6616.75
	Min, Max	358.4, 25222.2	389.0, 28916.1	414.7, 18053.0
	Mean (SD)	3798.31 (3797.909)	7756.44 (6088.749)	4752.88 (3667.383)
	95% CI of Mean	2942.01, 4654.61	5834.59, 9678.30	3547.44, 5958.33

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set****Parameter (units): B[a]P (fg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		30		21	
	Missing, n (%)	8 (10.7)		5 (14.3)		3 (12.5)	
	BLOQ, n(%)	2 (3.0)		1 (3.3)		0	
	Geometric Mean (CV%)	135.23 (83.511)		132.19 (72.132)		86.69 (64.125)	
	95% CI of Geometric Mean	113.24, 161.49		103.81, 168.33		66.36, 113.24	
	Median	144.74		143.72		82.78	
	Q25, Q75	82.52, 215.53		79.07, 205.61		60.65, 140.24	
	Min, Max	17.7, 778.0		29.6, 454.8		27.0, 225.8	
	Mean (SD)	172.63 (128.867)		159.33 (97.717)		101.97 (60.425)	
	95% CI of Mean	141.19, 204.07		122.84, 195.82		74.46, 129.48	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set****Parameter (units): B[a]P (fg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	13 (17.8)		3 (8.8)		6 (27.3)	
	Geometric Mean (CV%)	57.67 (93.709)		105.64 (84.094)		31.88 (117.245)	
	95% CI of Geometric Mean	47.91, 69.41		81.84, 136.35		21.10, 48.16	
	Median	59.27	-59.85	115.62	-11.13	27.09	-64.15
	Q25, Q75	37.83, 89.15	-67.95, -46.56	70.04, 180.31	-27.46, 4.57	14.27, 67.23	-75.84, -61.45
	Min, Max	9.8, 399.7	-87.0, 276.6	15.9, 387.4	-62.0, 47.6	6.1, 276.8	-86.9, 206.8
	Mean (SD)	78.77 (71.862)	-49.25 (47.787)	133.13 (89.049)	-11.00 (28.406)	48.79 (56.995)	-51.28 (61.708)
	95% CI of Mean	62.00, 95.54	-60.92, -37.59	102.06, 164.21	-21.61, -0.39	23.52, 74.07	-79.37, -23.19

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set****Parameter (units): B[a]P (fg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	27 (37.0)		1 (2.9)		11 (50.0)	
	Geometric Mean (CV%)	41.95 (115.197)		110.94 (81.167)		25.68 (106.108)	
	95% CI of Geometric Mean	33.85, 51.99		86.55, 142.21		17.47, 37.75	
	Median	37.66	-71.33	122.75	-7.83	22.31	-74.18
	Q25, Q75	19.94, 92.63	-83.58, -38.71	79.40, 203.29	-34.79, 7.17	14.27, 53.01	-82.76, -47.96
	Min, Max	7.5, 232.7	-95.4, 250.3	19.4, 339.5	-68.0, 201.1	8.0, 185.9	-93.0, 121.4
	Mean (SD)	62.69 (56.845)	-54.92 (49.326)	136.82 (82.609)	3.19 (57.095)	39.05 (44.948)	-51.91 (58.931)
	95% CI of Mean	49.42, 75.96	-66.95, -42.88	107.99, 165.65	-18.13, 24.52	19.11, 58.98	-78.74, -25.08

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set****Parameter (units): B[a]P (fg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	26 (35.6)		1 (2.9)		10 (45.5)	
	Geometric Mean (CV%)	36.96 (105.268)		105.14 (75.890)		25.04 (92.124)	
	95% CI of Geometric Mean	30.21, 45.22		83.09, 133.05		17.68, 35.45	
	Median	33.20	-72.83	115.41	-15.33	25.57	-71.03
	Q25, Q75	20.46, 74.85	-84.57, -48.95	65.85, 157.83	-21.97, 5.02	14.76, 37.43	-81.97, -61.57
	Min, Max	4.3, 264.9	-97.0, 31.7	22.0, 370.0	-80.1, 75.0	5.7, 117.5	-92.8, 80.1
	Mean (SD)	53.23 (49.580)	-63.04 (29.787)	128.61 (81.182)	-11.25 (31.636)	33.82 (29.546)	-58.69 (43.249)
	95% CI of Mean	41.66, 64.81	-70.31, -55.77	100.28, 156.94	-23.07, 0.56	20.71, 46.92	-78.38, -39.00

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set****Parameter (units): B[a]P (fg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	32 (43.8)		2 (5.9)		15 (68.2)	
	Geometric Mean (CV%)	30.51 (76.290)		100.86 (76.304)		19.61 (83.161)	
	95% CI of Geometric Mean	26.05, 35.74		79.63, 127.76		14.21, 27.05	
	Median	28.34	-77.44	116.16	-12.29	18.01	-81.64
	Q25, Q75	19.08, 56.36	-84.97, -66.41	62.76, 153.37	-24.54, 4.20	11.36, 41.45	-87.20, -68.68
	Min, Max	6.1, 143.7	-94.8, 57.3	25.4, 378.7	-79.1, 38.0	5.1, 72.3	-93.3, -19.8
	Mean (SD)	38.23 (26.991)	-72.74 (21.723)	123.77 (79.019)	-15.45 (27.758)	25.11 (18.378)	-71.88 (22.111)
	95% CI of Mean	31.93, 44.54	-78.04, -67.44	96.19, 151.34	-25.82, -5.08	16.96, 33.27	-81.95, -61.81

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set****Parameter (units): B[a]P (fg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	42 (57.5)		5 (14.7)		17 (77.3)	
	Geometric Mean (CV%)	33.44 (61.495)		107.09 (88.179)		18.34 (77.809)	
	95% CI of Geometric Mean	29.29, 38.16		82.19, 139.54		13.51, 24.88	
	Median	31.87	-75.98	129.77	-4.92	16.47	-81.45
	Q25, Q75	21.44, 49.60	-84.80, -64.75	62.61, 202.81	-20.81, 3.94	11.47, 29.76	-84.73, -77.55
	Min, Max	9.8, 110.0	-95.3, 37.3	30.5, 338.9	-74.8, 46.5	4.6, 64.2	-94.3, -28.8
	Mean (SD)	39.23 (23.558)	-68.31 (27.181)	137.23 (90.210)	-8.68 (26.123)	23.08 (16.828)	-75.41 (17.721)
	95% CI of Mean	33.73, 44.73	-74.94, -61.67	105.74, 168.71	-18.44, 1.08	15.62, 30.55	-83.48, -67.34

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set****Parameter (units): B[a]P (fg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		29		12	
	Missing, n (%)	3 (7.5)		5 (14.7)		1 (7.7)	
	BLOQ, n(%)	0		1 (3.4)		0	
	Geometric Mean (CV%)	155.02 (76.043)		127.04 (77.294)		100.45 (54.137)	
	95% CI of Geometric Mean	123.75, 194.18		97.92, 164.82		72.78, 138.62	
	Median	144.74		143.38		92.14	
	Q25, Q75	113.89, 229.38		79.07, 190.07		66.08, 158.71	
	Min, Max	44.3, 778.0		29.6, 454.8		49.9, 215.3	
	Mean (SD)	194.33 (147.518)		155.88 (99.355)		113.05 (57.756)	
	95% CI of Mean	145.14, 243.52		118.08, 193.68		76.35, 149.75	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set****Parameter (units): B[a]P (fg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	37	33	29	13	12
	Missing, n (%)	0	3 (7.5)	1 (2.9)	5 (14.7)	0	1 (7.7)
	BLOQ, n(%)	11 (27.5)		1 (3.0)		3 (23.1)	
	Geometric Mean (CV%)	55.41 (106.013)		125.37 (79.773)		45.53 (68.828)	
	95% CI of Geometric Mean	41.97, 73.14		97.74, 160.79		31.24, 66.33	
	Median	56.35	-65.44	137.30	4.32	46.50	-50.53
	Q25, Q75	30.57, 100.03	-79.08, -27.55	73.64, 181.28	-13.72, 20.22	35.92, 65.64	-78.88, -16.44
	Min, Max	9.8, 338.7	-95.0, 98.4	33.6, 651.1	-64.8, 448.4	11.9, 116.9	-89.7, 134.3
	Mean (SD)	79.92 (76.667)	-50.61 (42.269)	158.86 (123.269)	21.77 (90.378)	53.64 (31.277)	-35.15 (62.987)
	95% CI of Mean	55.40, 104.45	-64.71, -36.52	115.14, 202.57	-12.62, 56.15	34.73, 72.55	-75.17, 4.88

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set****Parameter (units): B[a]P (fg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	35		30		11	
	Missing, n (%)	4 (10.3)		5 (14.3)		1 (8.3)	
	BLOQ, n(%)	0		1 (3.3)		0	
	Geometric Mean (CV%)	154.19 (77.400)		123.53 (78.051)		94.88 (53.074)	
	95% CI of Geometric Mean	121.85, 195.11		95.48, 159.83		67.89, 132.61	
	Median	144.74		142.67		88.60	
	Q25, Q75	113.89, 229.38		77.24, 190.07		62.39, 140.37	
	Min, Max	45.7, 778.0		29.6, 454.8		49.9, 215.3	
	Mean (SD)	194.31 (149.520)		152.51 (99.353)		106.73 (56.918)	
	95% CI of Mean	142.94, 245.68		115.41, 189.62		68.49, 144.98	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set****Parameter (units): B[a]P (fg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	35	34	30	11	11
	Missing, n (%)	0	4 (10.3)	1 (2.9)	5 (14.3)	1 (8.3)	1 (8.3)
	BLOQ, n(%)	7 (17.9)		2 (5.9)		4 (36.4)	
	Geometric Mean (CV%)	58.51 (83.107)		117.98 (88.600)		41.36 (129.727)	
	95% CI of Geometric Mean	46.26, 74.01		90.45, 153.87		21.21, 80.62	
	Median	62.64	-64.34	151.13	1.13	37.01	-58.23
	Q25, Q75	35.27, 96.73	-78.87, -33.75	79.66, 183.59	-31.48, 21.49	18.66, 79.17	-82.09, -39.02
	Min, Max	13.3, 300.3	-95.1, 108.6	20.8, 496.1	-64.8, 423.3	12.5, 315.2	-90.7, 531.8
	Mean (SD)	74.59 (55.044)	-48.90 (46.346)	150.46 (101.976)	19.15 (96.436)	68.65 (88.040)	-4.41 (179.712)
	95% CI of Mean	56.74, 92.43	-64.82, -32.97	114.88, 186.05	-16.86, 55.17	9.50, 127.80	-125.14, 116.33

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set****Parameter (units): B[a]P (fg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	43		29		9	
	Missing, n (%)	4 (8.5)		3 (9.4)		0	
	BLOQ, n(%)	0		1 (3.4)		0	
	Geometric Mean (CV%)	157.19 (73.836)		118.11 (73.294)		90.52 (50.733)	
	95% CI of Geometric Mean	128.31, 192.58		92.03, 151.57		62.65, 130.77	
	Median	145.11		141.97		88.60	
	Q25, Q75	113.89, 229.38		77.24, 181.40		62.39, 129.82	
	Min, Max	45.7, 778.0		29.6, 352.3		49.9, 215.3	
	Mean (SD)	194.60 (141.463)		142.09 (82.747)		100.79 (53.071)	
	95% CI of Mean	151.06, 238.15		110.61, 173.57		59.99, 141.59	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set****Parameter (units): B[a]P (fg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	43	32	29	9	9
	Missing, n (%)	0	4 (8.5)	0	3 (9.4)	0	
	BLOQ, n(%)	9 (19.1)		2 (6.3)		2 (22.2)	
	Geometric Mean (CV%)	61.27 (92.924)		116.04 (88.286)		46.50 (41.107)	
	95% CI of Geometric Mean	48.60, 77.25		88.25, 152.58		34.32, 63.01	
	Median	62.77	-58.58	133.14	7.59	47.28	-47.56
	Q25, Q75	36.70, 107.82	-77.74, -36.49	59.25, 213.33	-25.84, 19.35	32.64, 59.74	-57.44, -26.98
	Min, Max	12.4, 426.3	-93.7, 93.6	28.9, 359.3	-76.2, 354.4	27.7, 89.5	-84.8, 12.2
	Mean (SD)	83.57 (76.416)	-50.86 (37.001)	149.79 (103.082)	18.37 (84.237)	49.86 (20.009)	-41.82 (28.013)
	95% CI of Mean	61.13, 106.01	-62.25, -39.47	112.62, 186.96	-13.68, 50.41	34.47, 65.24	-63.36, -20.29

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set**

Parameter (units): B[a]P (pg)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	69	30	21
	Missing, n (%)	6 (8.0)	5 (14.3)	3 (12.5)
	BLOQ, n(%)	2 (2.9)	1 (3.3)	0
	Geometric Mean (CV%)	224.31 (76.987)	209.57 (58.890)	139.00 (48.255)
	95% CI of Geometric Mean	190.40, 264.27	170.94, 256.94	112.86, 171.19
	Median	222.16	219.47	137.74
	Q25, Q75	142.80, 369.50	160.06, 332.52	105.47, 194.60
	Min, Max	36.6, 919.8	59.8, 651.9	56.3, 336.6
	Mean (SD)	278.28 (188.467)	240.21 (128.577)	153.33 (70.235)
	95% CI of Mean	233.00, 323.56	192.19, 288.23	121.35, 185.30

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set**

Parameter (units): B[a]P (pg)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n(%)	13 (17.8)	3 (8.8)	6 (27.3)
	Geometric Mean (CV%)	94.95 (85.201)	169.95 (78.294)	51.50 (97.024)
	95% CI of Geometric Mean	79.91, 112.81	133.51, 216.32	35.88, 73.90
	Median	91.29	194.05	59.51
	Q25, Q75	70.58, 147.95	99.97, 279.40	30.39, 82.55
	Min, Max	18.7, 547.0	24.7, 609.5	9.1, 357.4
	Mean (SD)	125.36 (109.471)	208.16 (128.204)	71.14 (71.999)
	95% CI of Mean	99.82, 150.91	163.42, 252.89	39.22, 103.07

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set**

Parameter (units): B[a]P (pg)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n(%)	27 (37.0)	1 (2.9)	10 (45.5)
	Geometric Mean (CV%)	69.49 (114.095)	180.79 (73.617)	43.39 (98.032)
	95% CI of Geometric Mean	56.15, 85.99	143.69, 227.46	30.15, 62.43
	Median	65.39	192.85	39.01
	Q25, Q75	32.10, 141.25	145.00, 324.52	22.81, 70.29
	Min, Max	13.4, 501.0	32.1, 487.7	13.1, 306.5
	Mean (SD)	105.29 (104.955)	215.27 (114.618)	63.07 (70.792)
	95% CI of Mean	80.80, 129.78	175.27, 255.27	31.68, 94.46

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set**

Parameter (units): B[a]P (pg)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n(%)	26 (35.6)	1 (2.9)	10 (45.5)
	Geometric Mean (CV%)	61.08 (98.946)	170.76 (69.156)	38.67 (98.939)
	95% CI of Geometric Mean	50.37, 74.07	137.29, 212.39	26.80, 55.78
	Median	54.30	189.08	37.17
	Q25, Q75	33.54, 95.77	121.63, 250.52	19.08, 59.45
	Min, Max	11.5, 457.8	50.6, 536.0	10.2, 279.8
	Mean (SD)	88.32 (89.789)	202.52 (115.081)	55.08 (58.521)
	95% CI of Mean	67.37, 109.28	162.36, 242.68	29.12, 81.03

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set**

Parameter (units): B[a]P (pg)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n(%)	32 (43.8)	2 (5.9)	15 (68.2)
	Geometric Mean (CV%)	50.74 (70.358)	160.71 (75.899)	30.74 (85.106)
	95% CI of Geometric Mean	43.75, 58.83	127.00, 203.35	22.16, 42.65
	Median	50.65	191.71	25.86
	Q25, Q75	30.26, 77.62	92.55, 252.90	16.85, 53.22
	Min, Max	12.5, 187.8	28.1, 554.5	10.6, 125.8
	Mean (SD)	62.15 (42.573)	194.88 (117.033)	40.63 (33.654)
	95% CI of Mean	52.21, 72.09	154.04, 235.72	25.70, 55.55

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set**

Parameter (units): B[a]P (pg)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	73	34	22
	Missing, n (%)	2 (2.7)	1 (2.9)	2 (8.3)
	BLOQ, n(%)	42 (57.5)	5 (14.7)	17 (77.3)
	Geometric Mean (CV%)	57.23 (54.236)	174.84 (81.218)	30.58 (67.524)
	95% CI of Geometric Mean	50.83, 64.43	136.39, 224.13	23.30, 40.13
	Median	52.51	200.33	26.62
	Q25, Q75	42.40, 80.86	108.18, 319.43	20.84, 35.80
	Min, Max	19.9, 163.8	36.8, 514.4	11.1, 116.5
	Mean (SD)	64.91 (33.611)	215.40 (124.988)	37.29 (27.356)
	95% CI of Mean	57.06, 72.76	171.79, 259.02	25.16, 49.43

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set**

Parameter (units): B[a]P (pg)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	38	29	12
	Missing, n (%)	2 (5.0)	5 (14.7)	1 (7.7)
	BLOQ, n(%)	0	1 (3.4)	0
	Geometric Mean (CV%)	257.79 (71.143)	208.30 (62.693)	157.36 (51.215)
	95% CI of Geometric Mean	208.88, 318.14	167.32, 259.30	115.80, 213.84
	Median	274.26	231.88	139.82
	Q25, Q75	174.28, 392.16	160.06, 332.52	109.88, 208.21
	Min, Max	55.8, 876.3	55.9, 651.9	81.8, 399.0
	Mean (SD)	311.63 (196.668)	241.34 (131.354)	176.83 (98.493)
	95% CI of Mean	246.98, 376.27	191.38, 291.31	114.25, 239.42

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set**

Parameter (units): B[a]P (pg)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Day 30	n	40	33	13
	Missing, n (%)	0	1 (2.9)	0
	BLOQ, n(%)	11 (27.5)	1 (3.0)	3 (23.1)
	Geometric Mean (CV%)	89.77 (114.134)	209.19 (69.077)	74.78 (76.370)
	95% CI of Geometric Mean	67.03, 120.23	167.63, 261.05	49.64, 112.64
	Median	92.06	211.59	74.12
	Q25, Q75	48.02, 178.02	145.64, 301.18	61.65, 112.83
	Min, Max	16.9, 464.1	65.6, 960.0	19.3, 224.9
	Mean (SD)	130.42 (113.249)	253.58 (177.334)	90.28 (55.054)
	95% CI of Mean	94.19, 166.64	190.70, 316.47	57.01, 123.56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set**

Parameter (units): B[a]P (pg)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	37	30	11
	Missing, n (%)	2 (5.1)	5 (14.3)	1 (8.3)
	BLOQ, n(%)	0	1 (3.3)	0
	Geometric Mean (CV%)	253.21 (76.653)	201.22 (65.375)	153.62 (53.748)
	95% CI of Geometric Mean	201.85, 317.63	161.04, 251.43	109.51, 215.50
	Median	270.47	219.47	132.26
	Q25, Q75	174.28, 392.16	137.56, 332.52	108.07, 225.34
	Min, Max	55.8, 876.3	55.9, 651.9	81.8, 399.0
	Mean (SD)	311.81 (201.369)	235.76 (132.640)	174.66 (103.548)
	95% CI of Mean	244.67, 378.95	186.23, 285.30	105.09, 244.23

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set**

Parameter (units): B[a]P (pg)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Day 60	n	39	34	11
	Missing, n (%)	0	1 (2.9)	1 (8.3)
	BLOQ, n(%)	7 (17.9)	2 (5.9)	4 (36.4)
	Geometric Mean (CV%)	94.81 (84.976)	197.50 (91.631)	69.08 (130.411)
	95% CI of Geometric Mean	74.65, 120.41	150.40, 259.35	35.36, 134.95
	Median	97.07	218.32	58.45
	Q25, Q75	55.39, 167.26	142.22, 321.22	27.56, 148.83
	Min, Max	20.5, 524.3	24.5, 826.6	19.2, 506.4
	Mean (SD)	122.66 (96.321)	252.89 (172.368)	114.17 (142.917)
	95% CI of Mean	91.43, 153.88	192.74, 313.04	18.15, 210.19

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set**

Parameter (units): B[a]P (pg)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	45	29	9
	Missing, n (%)	2 (4.3)	3 (9.4)	0
	BLOQ, n(%)	0	1 (3.4)	0
	Geometric Mean (CV%)	254.90 (74.740)	193.23 (61.130)	146.81 (49.648)
	95% CI of Geometric Mean	208.66, 311.38	155.95, 239.42	102.34, 210.60
	Median	270.47	207.06	132.26
	Q25, Q75	174.28, 384.43	137.56, 291.91	111.68, 163.62
	Min, Max	55.8, 919.8	55.9, 447.9	81.8, 399.0
	Mean (SD)	313.55 (208.789)	221.41 (108.735)	164.36 (96.997)
	95% CI of Mean	250.82, 376.28	180.05, 262.78	89.80, 238.93

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.1 Descriptive Statistics of B[a]P in 24-hour Urine Collection - PP Set**

Parameter (units): B[a]P (pg)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Day 90	n	47	32	9
	BLOQ, n(%)	9 (19.1)	2 (6.3)	2 (22.2)
	Geometric Mean (CV%)	103.55 (93.875)	193.22 (81.367)	79.60 (51.557)
	95% CI of Geometric Mean	81.99, 130.78	149.43, 249.84	54.81, 115.62
	Median	97.33	197.01	74.48
	Q25, Q75	74.38, 173.40	105.06, 340.13	60.33, 114.36
	Min, Max	19.7, 684.6	34.5, 709.9	35.0, 163.5
	Mean (SD)	142.17 (131.066)	242.66 (164.542)	88.24 (42.588)
	95% CI of Mean	103.69, 180.66	183.33, 301.99	55.50, 120.98

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (fg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		36		36	
	Missing, n (%)	9 (11.3)		5 (12.2)		3 (7.7)	
	BLOQ, n(%)	2 (2.8)		2 (5.6)		0	
	Geometric Mean (CV%)	135.78 (82.312)		125.34 (77.046)		106.40 (66.393)	
	95% CI of Geometric Mean	114.52, 160.99		99.49, 157.92		86.72, 130.54	
	Median	144.74		143.72		108.71	
	Q25, Q75	82.52, 217.89		78.15, 190.00		67.50, 174.90	
	Min, Max	17.7, 778.0		29.6, 454.8		27.0, 251.7	
	Mean (SD)	172.35 (126.595)		153.15 (94.077)		125.47 (69.457)	
	95% CI of Mean	142.38, 202.32		121.31, 184.98		101.97, 148.98	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (fg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	13 (16.9)		4 (10.0)		8 (21.6)	
	Geometric Mean (CV%)	58.12 (93.519)		102.64 (83.445)		42.66 (125.781)	
	95% CI of Geometric Mean	48.54, 69.58		81.35, 129.51		30.83, 59.04	
	Median	59.27	-59.76	119.12	-12.27	47.87	-64.03
	Q25, Q75	37.19, 89.71	-67.95, -46.56	66.13, 157.73	-27.02, 4.34	22.52, 83.64	-75.36, -38.04
	Min, Max	9.8, 399.7	-87.0, 276.6	15.9, 387.4	-62.0, 47.6	6.1, 276.8	-86.9, 206.8
	Mean (SD)	79.22 (71.213)	-49.39 (46.531)	128.92 (84.958)	-10.20 (28.022)	65.66 (65.367)	-48.17 (51.699)
	95% CI of Mean	63.05, 95.39	-60.40, -38.37	101.74, 156.09	-19.69, -0.72	43.86, 87.46	-65.66, -30.67

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (fg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	28 (36.4)		1 (2.5)		15 (40.5)	
	Geometric Mean (CV%)	43.07 (114.971)		112.28 (77.093)		37.10 (145.601)	
	95% CI of Geometric Mean	34.97, 53.05		90.25, 139.70		25.99, 52.95	
	Median	37.96	-70.88	125.10	-5.22	41.25	-70.42
	Q25, Q75	21.37, 99.49	-83.45, -38.71	79.79, 192.96	-29.87, 25.21	14.55, 72.25	-82.10, 0.00
	Min, Max	7.5, 232.7	-95.4, 250.3	19.4, 339.5	-68.0, 207.9	5.2, 285.1	-96.0, 121.4
	Mean (SD)	63.99 (56.727)	-54.19 (48.790)	136.22 (78.483)	9.48 (62.867)	64.00 (71.731)	-44.27 (53.441)
	95% CI of Mean	51.11, 76.87	-65.75, -42.64	111.11, 161.32	-11.80, 30.76	40.08, 87.93	-62.36, -26.18

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (fg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	27 (35.1)		2 (5.0)		14 (37.8)	
	Geometric Mean (CV%)	37.84 (107.229)		106.14 (79.088)		35.41 (121.168)	
	95% CI of Geometric Mean	31.02, 46.16		84.93, 132.65		25.79, 48.62	
	Median	33.88	-72.83	120.21	-10.68	32.97	-69.73
	Q25, Q75	20.46, 74.87	-84.07, -48.86	69.01, 169.14	-21.85, 6.85	16.85, 71.69	-80.52, -30.43
	Min, Max	4.3, 264.9	-97.0, 31.7	22.0, 370.0	-80.1, 138.5	5.7, 242.5	-92.8, 80.1
	Mean (SD)	54.79 (50.388)	-62.30 (30.015)	130.65 (80.628)	-4.79 (40.262)	55.19 (58.165)	-52.32 (41.090)
	95% CI of Mean	43.34, 66.23	-69.41, -55.19	104.86, 156.44	-18.41, 8.84	35.79, 74.58	-66.23, -38.41

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (fg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	34 (44.2)		3 (7.5)		20 (54.1)	
	Geometric Mean (CV%)	30.72 (78.309)		100.77 (75.603)		27.81 (118.920)	
	95% CI of Geometric Mean	26.25, 35.95		81.26, 124.95		20.33, 38.04	
	Median	28.34	-78.07	116.63	-9.20	22.77	-79.37
	Q25, Q75	19.08, 56.36	-84.97, -66.41	61.23, 156.45	-24.34, 5.14	14.04, 45.95	-86.20, -49.81
	Min, Max	6.1, 155.0	-94.8, 57.3	25.4, 378.7	-79.1, 77.7	5.1, 242.5	-93.3, 0.0
	Mean (SD)	39.12 (29.678)	-72.62 (21.655)	123.00 (75.994)	-11.50 (29.994)	44.86 (55.076)	-63.87 (31.478)
	95% CI of Mean	32.38, 45.86	-77.75, -67.49	98.69, 147.31	-21.65, -1.35	26.49, 63.23	-74.52, -53.21

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (fg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	44 (57.1)		6 (15.0)		24 (64.9)	
	Geometric Mean (CV%)	34.16 (62.876)		106.12 (87.767)		26.24 (116.159)	
	95% CI of Geometric Mean	29.96, 38.95		83.33, 135.14		19.28, 35.72	
	Median	32.22	-75.88	129.77	-4.92	21.32	-80.51
	Q25, Q75	22.40, 49.60	-84.80, -63.63	64.11, 195.76	-20.27, 7.61	12.68, 46.77	-85.34, -62.65
	Min, Max	9.8, 148.1	-95.3, 37.3	24.4, 338.9	-74.8, 96.8	4.6, 242.5	-94.3, 0.0
	Mean (SD)	40.50 (26.099)	-67.81 (26.840)	135.32 (86.937)	-5.38 (30.283)	42.70 (54.963)	-66.42 (30.645)
	95% CI of Mean	34.57, 46.43	-74.17, -61.45	107.51, 163.13	-15.63, 4.87	24.37, 61.03	-76.79, -56.05

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (fg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	16 (20.8)		1 (2.5)		6 (16.2)	
	Geometric Mean (CV%)	59.64 (90.875)		124.47 (78.115)		54.35 (92.216)	
	95% CI of Geometric Mean	50.00, 71.12		99.81, 155.22		41.84, 70.61	
	Median	61.85	-51.08	140.15	2.16	55.37	-48.02
	Q25, Q75	37.83, 100.26	-73.42, -27.50	71.81, 190.29	-13.83, 20.96	35.92, 102.07	-73.98, 0.00
	Min, Max	9.8, 338.7	-95.0, 98.4	33.6, 651.1	-64.8, 448.4	9.0, 242.5	-89.7, 134.3
	Mean (SD)	79.75 (65.934)	-44.98 (38.432)	155.92 (115.505)	18.41 (81.960)	71.24 (54.143)	-33.39 (52.719)
	95% CI of Mean	64.78, 94.72	-54.08, -35.88	118.97, 192.86	-9.32, 46.15	53.18, 89.30	-51.23, -15.54

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (fg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	11 (14.3)		3 (7.5)		7 (18.9)	
	Geometric Mean (CV%)	57.97 (85.984)		120.91 (87.460)		56.47 (107.847)	
	95% CI of Geometric Mean	48.96, 68.64		95.01, 153.87		42.13, 75.69	
	Median	57.19	-55.47	151.13	1.23	60.07	-49.55
	Q25, Q75	36.63, 98.40	-77.03, -28.50	80.42, 200.42	-23.77, 21.63	31.89, 93.78	-67.17, 0.00
	Min, Max	9.8, 458.3	-95.1, 234.4	20.8, 496.1	-64.8, 423.3	11.1, 315.2	-91.7, 531.8
	Mean (SD)	76.31 (66.806)	-42.37 (53.642)	152.96 (99.052)	17.13 (88.801)	81.47 (76.155)	-17.24 (111.829)
	95% CI of Mean	61.14, 91.48	-55.07, -29.67	121.27, 184.64	-12.92, 47.18	56.07, 106.86	-55.09, 20.60

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (fg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	15 (19.5)		3 (7.5)		8 (21.6)	
	Geometric Mean (CV%)	63.22 (105.901)		118.21 (86.991)		52.70 (90.789)	
	95% CI of Geometric Mean	51.92, 76.98		92.98, 150.29		40.69, 68.25	
	Median	63.66	-47.45	137.10	6.57	59.74	-52.04
	Q25, Q75	36.70, 117.12	-74.65, -24.15	59.25, 213.33	-25.19, 22.23	29.52, 89.49	-64.57, -11.89
	Min, Max	9.8, 641.5	-93.7, 458.8	28.9, 359.3	-76.2, 354.4	9.7, 242.5	-89.1, 46.6
	Mean (SD)	92.13 (97.288)	-32.78 (76.948)	150.61 (97.463)	14.44 (77.197)	69.41 (54.108)	-40.47 (33.147)
	95% CI of Mean	70.05, 114.22	-51.00, -14.56	119.44, 181.79	-11.68, 40.57	51.36, 87.46	-51.69, -29.25

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (pg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	73	36	36
	Missing, n (%)	7 (8.8)	5 (12.2)	3 (7.7)
	BLOQ, n(%)	2 (2.7)	2 (5.6)	0
	Geometric Mean (CV%)	225.47 (74.917)	200.33 (65.810)	174.12 (59.959)
	95% CI of Geometric Mean	192.95, 263.47	163.53, 245.42	144.34, 210.03
	Median	222.16	231.30	163.95
	Q25, Q75	151.15, 362.88	148.81, 312.21	115.75, 251.36
	Min, Max	36.6, 919.8	52.6, 651.9	56.3, 565.2
	Mean (SD)	277.21 (184.177)	234.02 (126.416)	203.12 (122.932)
	95% CI of Mean	234.23, 320.18	191.24, 276.80	161.52, 244.72

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (pg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 1	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n(%)	13 (16.9)	4 (10.0)	8 (21.6)
	Geometric Mean (CV%)	95.44 (84.309)	165.02 (78.056)	71.00 (110.751)
	95% CI of Geometric Mean	80.81, 112.72	132.35, 205.76	52.68, 95.68
	Median	91.29	194.05	75.53
	Q25, Q75	70.58, 147.95	99.47, 261.76	34.84, 127.55
	Min, Max	18.7, 547.0	24.7, 609.5	9.1, 540.6
	Mean (SD)	125.38 (107.878)	201.79 (122.812)	103.94 (105.149)
	95% CI of Mean	100.89, 149.87	162.51, 241.07	68.88, 139.01

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (pg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 2	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n(%)	28 (36.4)	1 (2.5)	14 (37.8)
	Geometric Mean (CV%)	71.10 (112.980)	182.80 (69.755)	62.81 (139.209)
	95% CI of Geometric Mean	57.86, 87.35	149.45, 223.58	44.43, 88.80
	Median	66.09	192.85	59.59
	Q25, Q75	33.26, 142.23	145.48, 306.41	29.93, 133.73
	Min, Max	13.4, 501.0	32.1, 487.7	9.7, 540.6
	Mean (SD)	106.69 (103.803)	214.77 (109.900)	105.13 (116.182)
	95% CI of Mean	83.12, 130.26	179.62, 249.92	66.38, 143.87

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (pg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 3	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n(%)	27 (35.1)	2 (5.0)	14 (37.8)
	Geometric Mean (CV%)	62.42 (99.845)	171.46 (70.456)	56.33 (127.547)
	95% CI of Geometric Mean	51.68, 75.40	139.95, 210.07	40.59, 78.18
	Median	54.91	190.23	50.68
	Q25, Q75	33.54, 98.46	122.43, 266.99	27.75, 118.77
	Min, Max	11.5, 457.8	45.7, 536.0	10.2, 540.6
	Mean (SD)	90.23 (89.802)	203.71 (112.964)	90.76 (104.138)
	95% CI of Mean	69.84, 110.62	167.57, 239.84	56.03, 125.48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (pg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 4	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n(%)	34 (44.2)	3 (7.5)	20 (54.1)
	Geometric Mean (CV%)	50.84 (71.755)	161.62 (73.544)	44.56 (123.303)
	95% CI of Geometric Mean	43.92, 58.85	130.96, 199.44	32.34, 61.41
	Median	50.63	196.00	36.53
	Q25, Q75	30.77, 77.62	93.34, 256.33	21.60, 82.74
	Min, Max	12.5, 212.9	28.1, 554.5	10.6, 540.6
	Mean (SD)	62.98 (45.264)	194.17 (112.422)	74.67 (100.014)
	95% CI of Mean	52.70, 73.26	158.21, 230.13	41.32, 108.02

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (pg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 5	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n(%)	44 (57.1)	6 (15.0)	24 (64.9)
	Geometric Mean (CV%)	58.37 (55.726)	174.35 (80.250)	44.51 (108.559)
	95% CI of Geometric Mean	51.87, 65.69	139.14, 218.45	33.16, 59.73
	Median	57.43	217.13	34.45
	Q25, Q75	42.94, 80.86	112.52, 302.39	25.43, 77.78
	Min, Max	19.9, 219.3	36.8, 514.4	11.1, 540.6
	Mean (SD)	66.83 (37.277)	213.66 (120.822)	71.60 (99.061)
	95% CI of Mean	58.37, 75.30	175.01, 252.30	38.57, 104.63

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (pg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n(%)	16 (20.8)	1 (2.5)	6 (16.2)
	Geometric Mean (CV%)	97.42 (90.881)	197.35 (74.465)	89.45 (88.324)
	95% CI of Geometric Mean	81.68, 116.19	159.58, 244.06	69.43, 115.22
	Median	103.96	200.46	104.97
	Q25, Q75	59.41, 176.51	135.77, 287.66	59.19, 137.68
	Min, Max	16.9, 464.1	31.8, 960.0	18.5, 540.6
	Mean (SD)	128.38 (96.561)	242.02 (168.170)	117.28 (97.124)
	95% CI of Mean	106.46, 150.31	188.24, 295.81	84.89, 149.66

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (pg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n(%)	11 (14.3)	3 (7.5)	7 (18.9)
	Geometric Mean (CV%)	93.55 (82.308)	196.98 (88.617)	95.79 (99.965)
	95% CI of Geometric Mean	79.45, 110.14	154.40, 251.28	72.57, 126.44
	Median	97.07	211.13	88.20
	Q25, Q75	62.44, 150.58	147.91, 338.59	58.34, 158.21
	Min, Max	20.5, 524.3	24.5, 826.6	19.2, 540.6
	Mean (SD)	119.59 (89.186)	249.64 (165.670)	135.00 (125.290)
	95% CI of Mean	99.34, 139.83	196.66, 302.63	93.22, 176.78

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.15.2 Descriptive Statistics of B[a]P in 24-hour Urine Collection - FAS****Parameter (units): B[a]P (pg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	77	40	37
	Missing, n (%)	3 (3.8)	1 (2.4)	2 (5.1)
	BLOQ, n(%)	15 (19.5)	3 (7.5)	8 (21.6)
	Geometric Mean (CV%)	106.83 (97.563)	187.44 (80.461)	86.30 (90.432)
	95% CI of Geometric Mean	88.72, 128.62	149.52, 234.97	66.69, 111.68
	Median	103.22	197.01	79.63
	Q25, Q75	71.60, 185.90	105.06, 326.03	59.19, 140.29
	Min, Max	18.7, 684.6	34.5, 709.9	20.1, 540.6
	Mean (SD)	146.91 (126.532)	234.17 (155.612)	115.31 (100.809)
	95% CI of Mean	118.19, 175.64	184.40, 283.94	81.69, 148.92

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set****Parameter (units): HMPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		30		21	
	Missing, n (%)	8 (10.7)		5 (14.3)		3 (12.5)	
	Geometric Mean (CV%)	297.82 (55.046)		312.55 (56.073)		304.27 (60.492)	
	95% CI of Geometric Mean	262.69, 337.64		257.11, 379.94		235.97, 392.34	
	Median	307.48		336.20		327.43	
	Q25, Q75	212.03, 402.68		217.57, 413.48		225.37, 387.35	
	Min, Max	89.4, 1173.2		69.6, 960.4		67.3, 785.5	
	Mean (SD)	337.88 (178.574)		353.87 (182.920)		347.87 (180.194)	
	95% CI of Mean	294.32, 381.44		285.56, 422.18		265.84, 429.90	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set****Parameter (units): HMPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	1 (1.4)		0		0	
	Geometric Mean (CV%)	121.53 (64.827)		296.99 (62.546)		112.35 (59.890)	
	95% CI of Geometric Mean	105.84, 139.55		243.03, 362.93		87.89, 143.61	
	Median	118.33	-54.53	320.94	-0.75	108.70	-68.17
	Q25, Q75	76.28, 176.87	-68.01, -41.66	216.67, 436.13	-22.98, 13.41	77.38, 193.18	-78.08, -40.74
	Min, Max	39.0, 581.2	-88.7, 21.6	53.6, 960.4	-58.3, 51.1	30.6, 242.6	-81.6, 162.3
	Mean (SD)	146.60 (103.708)	-52.58 (22.064)	342.73 (182.084)	-2.99 (27.066)	128.65 (64.922)	-51.08 (52.754)
	95% CI of Mean	122.40, 170.81	-57.97, -47.19	279.20, 406.27	-13.10, 7.12	99.86, 157.44	-75.10, -27.07

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set****Parameter (units): HMPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	3 (4.1)		0		1 (4.5)	
	Geometric Mean (CV%)	67.21 (68.238)		251.66 (58.497)		66.52 (83.137)	
	95% CI of Geometric Mean	58.17, 77.64		208.26, 304.11		48.23, 91.73	
	Median	62.61	-78.08	262.30	-26.39	59.60	-79.85
	Q25, Q75	49.32, 83.68	-84.93, -65.29	176.69, 355.72	-37.35, 1.89	43.55, 72.26	-84.90, -72.23
	Min, Max	7.9, 420.8	-92.2, 56.6	83.6, 960.4	-64.1, 102.1	20.7, 669.0	-92.2, 38.6
	Mean (SD)	82.81 (68.373)	-70.81 (23.638)	291.00 (173.520)	-11.84 (41.539)	96.12 (135.060)	-71.78 (27.596)
	95% CI of Mean	66.85, 98.76	-76.58, -65.03	230.46, 351.55	-27.36, 3.67	36.23, 156.01	-84.35, -59.21

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set****Parameter (units): HMPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	1 (1.4)		0		1 (4.5)	
	Geometric Mean (CV%)	103.21 (77.002)		288.53 (64.853)		86.44 (85.896)	
	95% CI of Geometric Mean	88.01, 121.03		234.64, 354.80		62.16, 120.19	
	Median	106.56	-61.35	277.63	-9.96	84.12	-73.84
	Q25, Q75	58.32, 176.00	-73.27, -46.60	210.26, 408.53	-26.48, 6.22	51.61, 163.06	-81.76, -56.50
	Min, Max	23.3, 489.0	-90.9, 44.5	51.1, 960.4	-51.2, 53.7	27.4, 341.7	-90.2, 2.6
	Mean (SD)	128.70 (87.308)	-56.88 (25.295)	337.74 (194.295)	-5.97 (26.916)	111.79 (82.466)	-65.09 (23.273)
	95% CI of Mean	108.32, 149.07	-63.05, -50.70	269.94, 405.54	-16.02, 4.09	75.23, 148.36	-75.69, -54.49

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set****Parameter (units): HMPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	0		0		2 (9.1)	
	Geometric Mean (CV%)	76.89 (53.708)		269.67 (64.103)		79.48 (69.057)	
	95% CI of Geometric Mean	68.36, 86.48		219.74, 330.94		60.25, 104.83	
	Median	77.71	-74.57	283.86	-9.62	77.53	-75.00
	Q25, Q75	55.33, 97.37	-82.74, -61.46	194.69, 406.93	-30.03, 5.24	52.00, 88.80	-82.50, -62.00
	Min, Max	27.9, 316.8	-90.9, 7.6	51.5, 960.4	-75.7, 67.3	28.4, 369.1	-89.0, -22.4
	Mean (SD)	88.06 (53.746)	-69.68 (19.288)	313.60 (176.093)	-10.54 (28.292)	98.44 (79.643)	-70.86 (17.059)
	95% CI of Mean	75.52, 100.61	-74.39, -64.97	252.15, 375.05	-21.11, 0.03	63.12, 133.76	-78.63, -63.09

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set****Parameter (units): HMPMA (ng/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	4 (5.5)		1 (2.9)		1 (4.5)	
	Geometric Mean (CV%)	95.35 (67.349)		270.99 (71.143)		84.11 (79.173)	
	95% CI of Geometric Mean	82.67, 109.98		216.76, 338.79		61.73, 114.60	
	Median	94.24	-69.37	311.19	-14.53	72.79	-76.45
	Q25, Q75	70.86, 139.67	-79.11, -52.89	204.43, 428.57	-34.06, 0.00	52.92, 147.04	-83.39, -64.75
	Min, Max	16.1, 334.6	-92.6, 46.5	24.4, 960.4	-64.9, 97.9	28.8, 316.7	-89.9, -18.9
	Mean (SD)	113.55 (68.330)	-63.03 (23.261)	316.15 (165.074)	-12.69 (31.585)	107.79 (85.220)	-68.67 (21.227)
	95% CI of Mean	97.60, 129.50	-68.71, -57.35	258.54, 373.75	-24.49, -0.89	70.01, 145.58	-78.34, -59.01

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set****Parameter (units): HMPMA (ng/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		29		12	
	Missing, n (%)	3 (7.5)		5 (14.7)		1 (7.7)	
	Geometric Mean (CV%)	312.28 (66.424)		291.11 (54.236)		298.50 (53.754)	
	95% CI of Geometric Mean	255.27, 382.03		239.97, 353.14		216.73, 411.12	
	Median	355.31		310.02		289.15	
	Q25, Q75	199.31, 475.00		217.09, 385.14		222.56, 353.52	
	Min, Max	89.4, 1173.2		69.6, 679.8		150.1, 785.5	
	Mean (SD)	368.71 (216.303)		325.72 (149.686)		338.31 (194.796)	
	95% CI of Mean	296.59, 440.83		268.78, 382.67		214.54, 462.08	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set**

Parameter (units): HMPMA (ng/mg creat)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	37	33	29	13	12
	Missing, n (%)	0	3 (7.5)	1 (2.9)	5 (14.7)	0	1 (7.7)
	Geometric Mean (CV%)	153.57 (56.567)		282.01 (59.221)		145.46 (74.603)	
	95% CI of Geometric Mean	129.75, 181.76		232.18, 342.54		97.31, 217.43	
	Median	158.59	-47.04	257.70	0.95	162.77	-49.77
	Q25, Q75	106.66, 208.33	-65.64, -32.02	203.31, 427.60	-22.67, 17.13	96.06, 216.77	-64.54, -34.25
	Min, Max	53.0, 457.5	-86.0, 54.5	74.5, 733.6	-51.4, 90.7	52.3, 408.8	-84.7, 1.7
	Mean (SD)	175.53 (94.692)	-40.85 (33.582)	325.17 (178.480)	-0.15 (30.549)	177.06 (114.084)	-47.57 (24.112)
	95% CI of Mean	145.24, 205.82	-52.06, -29.65	261.88, 388.47	-11.78, 11.47	108.12, 246.01	-62.90, -32.25

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set****Parameter (units): HMPMA (ng/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	35		30		11	
	Missing, n (%)	4 (10.3)		5 (14.3)		1 (8.3)	
	Geometric Mean (CV%)	304.80 (61.587)		292.75 (53.283)		258.06 (66.595)	
	95% CI of Geometric Mean	250.85, 370.36		242.89, 352.83		171.77, 387.70	
	Median	322.99		318.95		259.36	
	Q25, Q75	199.31, 460.53		217.09, 385.14		219.75, 340.85	
	Min, Max	91.6, 1173.2		69.6, 679.8		67.3, 785.5	
	Mean (SD)	355.79 (213.179)		326.35 (147.123)		301.25 (182.996)	
	95% CI of Mean	282.55, 429.02		271.41, 381.29		178.31, 424.19	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set****Parameter (units): HMPMA (ng/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	35	34	30	11	11
	Missing, n (%)	0	4 (10.3)	1 (2.9)	5 (14.3)	1 (8.3)	1 (8.3)
	BLOQ, n(%)	2 (5.1)		0		0	
	Geometric Mean (CV%)	109.98 (91.621)		229.88 (63.858)		96.05 (62.815)	
	95% CI of Geometric Mean	85.39, 141.66		187.44, 281.92		65.19, 141.51	
	Median	116.20	-63.17	244.22	-12.95	89.38	-61.68
	Q25, Q75	59.67, 206.25	-79.11, -41.57	172.32, 327.10	-38.10, -0.66	52.80, 141.43	-76.57, -43.19
	Min, Max	14.1, 410.6	-92.1, 58.7	49.3, 592.5	-65.7, 71.8	47.7, 250.7	-82.0, -23.4
	Mean (SD)	143.39 (101.698)	-49.55 (38.292)	265.47 (132.756)	-12.56 (33.335)	112.00 (67.109)	-58.68 (19.836)
	95% CI of Mean	110.42, 176.36	-62.71, -36.39	219.15, 311.80	-25.02, -0.11	66.91, 157.09	-72.01, -45.35

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set****Parameter (units): HMPMA (ng/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	43		29		9	
	Missing, n (%)	4 (8.5)		3 (9.4)		0	
	Geometric Mean (CV%)	312.73 (60.569)		289.28 (53.827)		254.00 (75.030)	
	95% CI of Geometric Mean	263.30, 371.45		238.77, 350.47		151.96, 424.54	
	Median	327.27		310.02		259.36	
	Q25, Q75	202.14, 475.00		217.09, 384.62		219.75, 327.43	
	Min, Max	91.6, 1173.2		69.6, 679.8		67.3, 785.5	
	Mean (SD)	362.02 (203.642)		323.34 (148.787)		305.28 (202.301)	
	95% CI of Mean	299.34, 424.70		266.74, 379.95		149.78, 460.79	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set****Parameter (units): HMPMA (ng/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	43	32	29	9	9
	Missing, n (%)	0	4 (8.5)	0	3 (9.4)	0	
	BLOQ, n(%)	1 (2.1)		1 (3.1)		1 (11.1)	
	Geometric Mean (CV%)	105.12 (73.418)		215.20 (78.533)		93.92 (100.445)	
	95% CI of Geometric Mean	86.68, 127.47		167.61, 276.30		49.42, 178.49	
	Median	125.78	-63.51	263.51	-26.81	73.48	-71.18
	Q25, Q75	62.89, 176.61	-76.31, -43.63	148.95, 342.10	-39.79, -6.00	68.36, 156.14	-72.56, -41.84
	Min, Max	23.5, 379.3	-93.9, 40.2	23.1, 620.8	-73.3, 99.6	22.1, 325.7	-89.9, 8.4
	Mean (SD)	127.73 (79.049)	-57.41 (26.094)	259.61 (144.408)	-18.97 (36.485)	124.88 (97.221)	-52.81 (34.899)
	95% CI of Mean	104.52, 150.95	-65.44, -49.37	207.54, 311.68	-32.85, -5.08	50.15, 199.62	-79.64, -25.98

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set**

Parameter (units): HMPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	70	31	22
	Missing, n (%)	5 (6.7)	4 (11.4)	2 (8.3)
	Geometric Mean (CV%)	502.16 (56.473)	507.60 (55.400)	484.85 (60.371)
	95% CI of Geometric Mean	442.95, 569.28	419.85, 613.68	378.67, 620.80
	Median	502.65	530.35	429.57
	Q25, Q75	382.53, 723.29	398.39, 730.32	354.59, 715.64
	Min, Max	162.6, 1674.6	79.0, 1055.6	100.4, 1199.2
	Mean (SD)	574.79 (315.062)	565.65 (246.705)	552.95 (276.481)
	95% CI of Mean	499.66, 649.92	475.16, 656.15	430.36, 675.54

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set**

Parameter (units): HMPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	1 (1.4)	0	0
	Geometric Mean (CV%)	202.59 (56.832)	489.57 (69.823)	186.24 (47.168)
	95% CI of Geometric Mean	179.22, 229.02	394.27, 607.89	153.42, 226.08
	Median	197.45	533.34	182.88
	Q25, Q75	138.97, 277.48	398.13, 736.45	145.47, 258.95
	Min, Max	68.7, 620.5	65.3, 1119.6	67.7, 462.6
	Mean (SD)	234.08 (137.670)	566.47 (265.122)	204.49 (91.327)
	95% CI of Mean	202.18, 265.98	475.39, 657.54	164.99, 243.99

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set**

Parameter (units): HMPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	3 (4.1)	0	1 (4.3)
	Geometric Mean (CV%)	112.00 (64.863)	418.25 (56.768)	108.30 (83.070)
	95% CI of Geometric Mean	97.63, 128.48	348.81, 501.53	79.17, 148.14
	Median	111.84	425.54	90.47
	Q25, Q75	83.95, 134.29	273.14, 598.09	81.07, 142.14
	Min, Max	11.5, 529.4	145.7, 975.9	37.1, 1482.8
	Mean (SD)	133.82 (94.958)	475.08 (234.195)	166.54 (291.851)
	95% CI of Mean	111.82, 155.83	394.63, 555.53	40.33, 292.75

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set**

Parameter (units): HMPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	1 (1.4)	0	1 (4.3)
	Geometric Mean (CV%)	172.55 (73.362)	477.84 (65.360)	130.20 (91.583)
	95% CI of Geometric Mean	148.21, 200.89	389.31, 586.49	92.90, 182.46
	Median	185.70	513.36	147.31
	Q25, Q75	111.01, 295.64	325.95, 751.30	68.70, 223.61
	Min, Max	42.7, 711.1	50.7, 1044.3	34.9, 478.5
	Mean (SD)	210.94 (134.852)	546.67 (248.913)	171.68 (128.307)
	95% CI of Mean	179.69, 242.19	461.16, 632.18	116.19, 227.17

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set**

Parameter (units): HMPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	0	0	2 (8.7)
	Geometric Mean (CV%)	128.34 (54.803)	438.13 (66.936)	124.30 (72.157)
	95% CI of Geometric Mean	113.96, 144.52	355.49, 539.98	93.94, 164.46
	Median	122.90	480.17	116.82
	Q25, Q75	94.40, 156.53	320.42, 717.96	82.25, 179.27
	Min, Max	43.2, 585.5	57.0, 919.8	34.0, 566.0
	Mean (SD)	148.91 (100.580)	505.93 (239.635)	155.45 (126.378)
	95% CI of Mean	125.60, 172.22	423.60, 588.25	100.80, 210.11

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set**

Parameter (units): HMPMA (ug)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	4 (5.4)	1 (2.9)	1 (4.3)
	Geometric Mean (CV%)	163.80 (64.163)	454.90 (76.208)	143.76 (79.094)
	95% CI of Geometric Mean	142.96, 187.68	360.54, 573.95	106.34, 194.33
	Median	158.78	478.72	119.75
	Q25, Q75	107.79, 269.61	406.85, 682.81	85.63, 258.03
	Min, Max	38.4, 574.4	29.4, 1171.5	40.4, 598.6
	Mean (SD)	192.77 (110.925)	532.19 (250.794)	181.94 (135.738)
	95% CI of Mean	167.06, 218.47	446.03, 618.34	123.24, 240.64

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set**

Parameter (units): HMPMA (ug)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	38	30	12
	Missing, n (%)	2 (5.0)	4 (11.8)	1 (7.7)
	Geometric Mean (CV%)	503.04 (65.778)	489.94 (57.734)	467.64 (51.281)
	95% CI of Geometric Mean	413.05, 612.64	401.02, 598.59	344.01, 635.68
	Median	532.60	504.73	406.17
	Q25, Q75	382.53, 762.48	390.44, 663.35	328.28, 703.32
	Min, Max	162.6, 1674.6	79.0, 1055.6	226.5, 1199.2
	Mean (SD)	593.52 (345.981)	551.42 (253.920)	523.11 (276.546)
	95% CI of Mean	479.80, 707.25	456.60, 646.24	347.40, 698.82

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set**

Parameter (units): HMPMA (ug)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Day 30	n	40	34	13
	Geometric Mean (CV%)	248.82 (61.924)	482.44 (60.948)	238.92 (61.494)
	95% CI of Geometric Mean	207.37, 298.56	396.52, 586.96	169.67, 336.43
	Median	249.45	448.82	313.21
	Q25, Q75	183.26, 367.10	340.83, 692.04	143.77, 333.66
	Min, Max	52.3, 786.5	86.7, 1357.5	93.1, 492.6
	Mean (SD)	288.26 (157.142)	557.27 (305.584)	273.20 (134.589)
	95% CI of Mean	237.99, 338.52	450.64, 663.90	191.86, 354.53

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set**

Parameter (units): HMPMA (ug)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	37	31	12
	Missing, n (%)	2 (5.1)	4 (11.4)	0
	Geometric Mean (CV%)	504.31 (61.458)	489.08 (56.632)	418.42 (67.106)
	95% CI of Geometric Mean	417.57, 609.07	403.05, 593.48	284.02, 616.40
	Median	499.71	479.11	404.23
	Q25, Q75	384.43, 725.55	390.44, 663.35	328.28, 636.38
	Min, Max	162.6, 1674.6	79.0, 1055.6	100.4, 1199.2
	Mean (SD)	587.53 (341.402)	548.60 (250.145)	488.39 (284.452)
	95% CI of Mean	473.70, 701.37	456.84, 640.36	307.66, 669.13

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set**

Parameter (units): HMPMA (ug)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Day 60	n	39	35	12
	BLOQ, n(%)	2 (5.1)	0	0
	Geometric Mean (CV%)	178.65 (86.974)	393.17 (72.889)	166.32 (46.768)
	95% CI of Geometric Mean	140.06, 227.86	314.19, 492.00	125.37, 220.64
	Median	167.60	381.92	170.26
	Q25, Q75	107.41, 340.79	283.13, 613.80	145.28, 214.57
	Min, Max	19.7, 628.2	66.1, 1223.9	73.8, 368.1
	Mean (SD)	226.46 (147.090)	472.44 (280.556)	181.33 (78.273)
	95% CI of Mean	178.77, 274.15	376.06, 568.82	131.59, 231.06

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set**

Parameter (units): HMPMA (ug)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	45	29	9
	Missing, n (%)	2 (4.3)	3 (9.4)	0
	Geometric Mean (CV%)	510.10 (59.959)	473.29 (56.259)	411.96 (79.727)
	95% CI of Geometric Mean	431.86, 602.51	387.70, 577.77	240.26, 706.36
	Median	531.33	463.98	383.29
	Q25, Q75	392.18, 723.29	390.44, 634.32	315.90, 691.00
	Min, Max	162.6, 1674.6	79.0, 1055.6	100.4, 1199.2
	Mean (SD)	588.23 (321.413)	529.93 (240.377)	501.46 (326.719)
	95% CI of Mean	491.66, 684.80	438.49, 621.37	250.32, 752.60

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.1 Descriptive Statistics of HMPMA in 24-hour Urine Collection - PP Set**

Parameter (units): HMPMA (ug)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Day 90	n	47	32	9
	BLOQ, n(%)	1 (2.1)	1 (3.1)	1 (11.1)
	Geometric Mean (CV%)	176.37 (64.216)	357.30 (81.221)	160.77 (76.072)
	95% CI of Geometric Mean	148.42, 209.59	276.42, 461.83	95.64, 270.27
	Median	164.63	377.59	167.44
	Q25, Q75	121.99, 265.41	257.35, 588.88	89.80, 266.26
	Min, Max	44.8, 448.6	27.6, 1091.0	60.5, 508.9
	Mean (SD)	206.12 (111.548)	433.54 (250.173)	197.28 (140.216)
	95% CI of Mean	173.36, 238.88	343.34, 523.74	89.50, 305.07

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		36		36	
	Missing, n (%)	9 (11.3)		5 (12.2)		3 (7.7)	
	Geometric Mean (CV%)	299.98 (55.198)		323.79 (56.104)		326.87 (56.355)	
	95% CI of Geometric Mean	265.50, 338.93		271.26, 386.49		273.65, 390.44	
	Median	307.48		348.52		338.22	
	Q25, Q75	212.03, 402.68		234.81, 461.95		249.85, 464.92	
	Min, Max	89.4, 1173.2		69.6, 960.4		67.3, 785.5	
	Mean (SD)	341.07 (183.186)		365.48 (178.436)		369.05 (178.019)	
	95% CI of Mean	297.70, 384.43		305.11, 425.86		308.82, 429.29	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	1 (1.3)		0		0	
	Geometric Mean (CV%)	122.13 (63.874)		308.70 (60.868)		131.48 (68.246)	
	95% CI of Geometric Mean	106.94, 139.48		257.96, 369.41		106.98, 161.59	
	Median	118.33	-55.96	348.84	-1.98	127.41	-64.16
	Q25, Q75	77.74, 177.50	-68.21, -41.66	217.00, 445.41	-18.74, 13.70	80.00, 204.68	-77.39, -38.15
	Min, Max	39.0, 581.2	-88.7, 21.6	53.6, 960.4	-58.3, 51.1	30.6, 508.0	-83.5, 162.3
	Mean (SD)	146.56 (101.820)	-52.60 (22.662)	353.34 (177.181)	-2.36 (25.602)	159.03 (108.332)	-48.19 (45.618)
	95% CI of Mean	123.44, 169.67	-57.97, -47.23	296.67, 410.01	-11.03, 6.31	122.91, 195.15	-63.63, -32.75

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	3 (3.9)		0		1 (2.7)	
	Geometric Mean (CV%)	68.65 (68.105)		267.81 (57.550)		81.89 (101.277)	
	95% CI of Geometric Mean	59.67, 78.98		225.70, 317.77		61.88, 108.37	
	Median	65.03	-78.08	282.08	-23.61	63.37	-78.76
	Q25, Q75	49.32, 87.97	-84.93, -64.09	180.00, 374.76	-32.80, 2.57	46.39, 111.16	-84.91, -60.29
	Min, Max	7.9, 420.8	-92.2, 56.6	83.6, 960.4	-64.1, 102.1	20.7, 669.0	-92.2, 38.6
	Mean (SD)	84.23 (67.445)	-70.37 (23.664)	307.23 (171.062)	-9.14 (41.356)	125.19 (148.875)	-64.19 (34.185)
	95% CI of Mean	68.92, 99.54	-75.97, -64.76	252.51, 361.94	-23.13, 4.86	75.55, 174.83	-75.77, -52.62

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	1 (1.3)		0		1 (2.7)	
	Geometric Mean (CV%)	107.14 (78.512)		310.14 (63.907)		105.40 (103.656)	
	95% CI of Geometric Mean	91.54, 125.40		257.20, 373.97		79.27, 140.14	
	Median	107.97	-61.20	329.94	-3.62	117.37	-70.33
	Q25, Q75	58.81, 193.33	-72.10, -46.24	227.35, 469.64	-24.59, 18.40	51.95, 200.62	-81.49, -47.55
	Min, Max	23.3, 489.0	-90.9, 47.0	51.1, 960.4	-51.2, 80.9	20.7, 508.0	-93.5, 2.6
	Mean (SD)	134.37 (91.603)	-55.23 (27.514)	360.20 (193.217)	-0.92 (29.853)	146.73 (121.027)	-57.41 (30.719)
	95% CI of Mean	113.58, 155.17	-61.75, -48.71	298.40, 421.99	-11.03, 9.18	106.37, 187.09	-67.81, -47.01

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	0		0		2 (5.4)	
	Geometric Mean (CV%)	77.37 (52.324)		281.34 (61.555)		96.45 (94.504)	
	95% CI of Geometric Mean	69.19, 86.52		234.69, 337.26		73.89, 125.89	
	Median	77.71	-74.57	319.16	-9.14	84.63	-73.88
	Q25, Q75	56.28, 97.37	-82.74, -61.46	197.46, 415.24	-27.55, 4.51	52.00, 150.55	-84.51, -48.92
	Min, Max	27.9, 316.8	-90.9, 7.6	51.5, 960.4	-75.7, 67.3	28.4, 508.0	-91.8, 0.0
	Mean (SD)	88.05 (52.405)	-69.82 (18.905)	323.15 (168.628)	-9.82 (26.581)	136.19 (130.071)	-61.54 (29.997)
	95% CI of Mean	76.15, 99.95	-74.30, -65.34	269.22, 377.09	-18.82, -0.82	92.82, 179.56	-71.69, -51.38

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	4 (5.2)		1 (2.5)		1 (2.7)	
	Geometric Mean (CV%)	98.21 (68.553)		293.59 (71.288)		109.05 (95.964)	
	95% CI of Geometric Mean	85.30, 113.07		239.17, 360.40		83.29, 142.77	
	Median	98.81	-68.76	331.79	-12.36	105.57	-73.27
	Q25, Q75	71.10, 146.04	-79.11, -52.89	231.60, 437.79	-31.01, 7.20	55.29, 214.04	-81.15, -35.75
	Min, Max	16.1, 405.8	-92.6, 93.1	24.4, 960.4	-64.9, 97.9	28.8, 508.0	-89.9, 0.0
	Mean (SD)	117.88 (74.545)	-60.98 (29.317)	344.41 (186.077)	-5.98 (37.860)	149.74 (124.766)	-58.09 (31.288)
	95% CI of Mean	100.96, 134.81	-67.92, -54.03	284.90, 403.93	-18.80, 6.83	108.14, 191.34	-68.68, -47.50

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	1 (1.3)		0		0	
	Geometric Mean (CV%)	147.50 (61.865)		308.40 (60.255)		174.09 (67.827)	
	95% CI of Geometric Mean	129.61, 167.84		258.11, 368.49		141.80, 213.73	
	Median	144.96	-47.55	286.46	0.32	183.01	-44.23
	Q25, Q75	109.16, 212.32	-65.06, -30.63	211.68, 452.22	-21.14, 16.87	108.62, 253.85	-66.52, -1.36
	Min, Max	19.6, 533.7	-90.7, 208.5	74.5, 960.4	-51.4, 90.7	52.3, 508.0	-84.7, 198.3
	Mean (SD)	171.55 (97.591)	-39.44 (42.576)	356.73 (196.734)	-1.18 (28.170)	207.54 (123.472)	-34.77 (49.822)
	95% CI of Mean	149.39, 193.70	-49.52, -29.36	293.80, 419.65	-10.72, 8.35	166.37, 248.71	-51.63, -17.91

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	2 (2.6)		0		0	
	Geometric Mean (CV%)	118.43 (81.515)		260.96 (69.941)		135.97 (69.533)	
	95% CI of Geometric Mean	100.71, 139.26		213.27, 319.33		110.27, 167.64	
	Median	120.56	-59.43	285.65	-11.61	133.55	-59.84
	Q25, Q75	71.08, 202.36	-74.89, -37.47	182.12, 437.87	-30.54, 4.49	89.38, 208.41	-73.55, -32.13
	Min, Max	14.1, 434.9	-92.1, 81.8	49.3, 960.4	-65.7, 71.8	47.7, 508.0	-87.5, 16.5
	Mean (SD)	148.95 (99.037)	-48.37 (36.906)	310.27 (179.886)	-10.33 (31.239)	165.40 (112.603)	-50.08 (29.468)
	95% CI of Mean	126.46, 171.43	-57.11, -39.63	252.74, 367.81	-20.90, 0.25	127.86, 202.95	-60.06, -40.11

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ng/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	2 (2.6)		1 (2.5)		1 (2.7)	
	Geometric Mean (CV%)	106.42 (80.338)		252.58 (81.316)		124.14 (94.841)	
	95% CI of Geometric Mean	90.67, 124.91		201.11, 317.22		95.04, 162.15	
	Median	120.31	-58.13	280.04	-18.70	131.99	-62.65
	Q25, Q75	65.54, 180.00	-75.76, -37.94	170.72, 431.56	-37.64, 0.39	72.89, 215.55	-77.63, -6.54
	Min, Max	10.2, 379.3	-96.7, 40.2	23.1, 960.4	-73.3, 99.6	22.1, 508.0	-92.9, 8.4
	Mean (SD)	131.66 (80.878)	-55.80 (25.657)	308.90 (183.288)	-16.12 (33.931)	164.85 (123.112)	-49.90 (34.401)
	95% CI of Mean	113.30, 150.02	-61.87, -49.72	250.28, 367.53	-27.60, -4.63	123.80, 205.90	-61.54, -38.25

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	74	37	37
	Missing, n (%)	6 (7.5)	4 (9.8)	2 (5.1)
	Geometric Mean (CV%)	505.80 (55.916)	527.44 (55.324)	531.60 (57.102)
	95% CI of Geometric Mean	448.23, 570.78	443.96, 626.61	445.31, 634.62
	Median	502.65	558.15	532.97
	Q25, Q75	382.53, 723.29	408.75, 730.32	383.29, 797.30
	Min, Max	162.6, 1674.6	79.0, 1123.2	100.4, 1286.4
	Mean (SD)	577.51 (312.238)	588.01 (253.585)	601.90 (291.752)
	95% CI of Mean	505.16, 649.85	503.46, 672.57	504.62, 699.18

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 1	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	1 (1.3)	0	0
	Geometric Mean (CV%)	202.94 (55.800)	506.24 (66.491)	221.19 (62.646)
	95% CI of Geometric Mean	180.46, 228.23	418.23, 612.78	183.07, 267.24
	Median	198.99	535.51	203.76
	Q25, Q75	138.97, 277.48	419.55, 736.45	148.12, 268.13
	Min, Max	68.7, 620.5	65.3, 1119.6	67.7, 1132.5
	Mean (SD)	233.40 (135.023)	580.07 (262.785)	267.33 (210.968)
	95% CI of Mean	202.95, 263.85	497.12, 663.02	197.98, 336.68

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 2	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	3 (3.8)	0	1 (2.6)
	Geometric Mean (CV%)	113.94 (64.187)	442.73 (55.393)	134.83 (104.457)
	95% CI of Geometric Mean	99.80, 130.08	376.03, 521.26	101.66, 178.82
	Median	113.27	476.43	94.70
	Q25, Q75	84.45, 136.18	324.58, 598.09	81.07, 194.56
	Min, Max	11.5, 529.4	145.7, 975.9	37.1, 1482.8
	Mean (SD)	135.50 (93.660)	499.30 (234.818)	219.63 (310.083)
	95% CI of Mean	114.38, 156.62	425.18, 573.42	117.71, 321.56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 3	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	1 (1.3)	0	1 (2.6)
	Geometric Mean (CV%)	178.61 (73.988)	508.57 (62.849)	164.19 (108.212)
	95% CI of Geometric Mean	153.88, 207.31	423.89, 610.16	122.93, 219.31
	Median	191.83	560.07	186.32
	Q25, Q75	112.36, 306.92	389.83, 751.30	75.33, 289.73
	Min, Max	42.7, 711.1	50.7, 1044.3	34.9, 1132.5
	Mean (SD)	218.49 (138.012)	576.31 (248.648)	238.58 (232.340)
	95% CI of Mean	187.37, 249.61	497.82, 654.80	162.20, 314.95

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 4	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	0	0	2 (5.3)
	Geometric Mean (CV%)	128.51 (53.322)	458.24 (63.362)	153.44 (103.251)
	95% CI of Geometric Mean	114.80, 143.85	381.46, 550.48	115.96, 203.02
	Median	124.93	487.60	120.70
	Q25, Q75	97.72, 156.53	336.76, 694.12	82.25, 211.36
	Min, Max	43.2, 585.5	57.0, 919.8	34.0, 1132.5
	Mean (SD)	148.10 (98.104)	521.99 (231.814)	232.08 (260.668)
	95% CI of Mean	125.98, 170.23	448.82, 595.17	146.39, 317.76

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 5	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	4 (5.1)	1 (2.4)	1 (2.6)
	Geometric Mean (CV%)	168.34 (65.277)	492.91 (75.009)	186.38 (94.613)
	95% CI of Geometric Mean	147.18, 192.55	399.19, 608.64	143.30, 242.40
	Median	163.92	575.64	186.21
	Q25, Q75	109.34, 270.51	410.01, 726.90	97.05, 310.59
	Min, Max	38.4, 647.4	29.4, 1454.2	40.4, 1132.5
	Mean (SD)	199.48 (120.015)	577.21 (284.087)	258.15 (238.431)
	95% CI of Mean	172.42, 226.55	487.53, 666.88	179.77, 336.52

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	1 (1.3)	0	0
	Geometric Mean (CV%)	243.45 (63.622)	498.71 (59.540)	285.38 (66.751)
	95% CI of Geometric Mean	213.46, 277.65	419.11, 593.42	233.75, 348.40
	Median	244.47	528.12	318.41
	Q25, Q75	177.81, 363.34	345.36, 771.19	185.30, 431.59
	Min, Max	35.9, 786.5	86.7, 1357.5	86.8, 1132.5
	Mean (SD)	284.00 (157.988)	571.65 (296.644)	340.75 (218.375)
	95% CI of Mean	248.37, 319.62	478.01, 665.29	268.97, 412.53

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	2 (2.6)	0	0
	Geometric Mean (CV%)	193.92 (77.275)	431.93 (72.822)	230.67 (67.292)
	95% CI of Geometric Mean	166.19, 226.27	351.56, 530.68	188.68, 281.99
	Median	183.58	458.53	222.66
	Q25, Q75	124.26, 335.94	318.11, 692.04	161.45, 358.61
	Min, Max	19.7, 782.5	66.1, 1223.9	73.8, 1132.5
	Mean (SD)	240.43 (160.298)	516.50 (290.748)	281.72 (214.708)
	95% CI of Mean	204.28, 276.58	424.72, 608.27	211.14, 352.30

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.16.2 Descriptive Statistics of HMPMA in 24-hour Urine Collection - FAS****Parameter (units): HMPMA (ug)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	2 (2.6)	1 (2.4)	1 (2.6)
	Geometric Mean (CV%)	181.58 (71.939)	406.57 (77.211)	203.70 (93.335)
	95% CI of Geometric Mean	156.97, 210.04	327.64, 504.52	157.03, 264.23
	Median	196.22	419.93	229.57
	Q25, Q75	122.19, 294.84	288.76, 692.04	121.42, 319.20
	Min, Max	22.9, 707.3	27.6, 1091.0	43.5, 1132.5
	Mean (SD)	218.58 (131.579)	483.80 (250.214)	273.29 (228.139)
	95% CI of Mean	188.91, 248.25	404.82, 562.78	198.30, 348.29

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set****Parameter (units): S-BMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	65		30		21	
	Missing, n (%)	10 (13.3)		5 (14.3)		3 (12.5)	
	Geometric Mean (CV%)	3855.95 (67.400)		3549.66 (42.877)		3944.45 (74.437)	
	95% CI of Geometric Mean	3313.41, 4487.33		3044.85, 4138.16		2915.56, 5336.43	
	Median	3790.95		3405.35		3935.19	
	Q25, Q75	2666.67, 5773.52		2662.16, 4605.01		2854.89, 4943.34	
	Min, Max	906.4, 16562.5		1688.4, 8363.6		1422.2, 15343.3	
	Mean (SD)	4628.37 (2997.844)		3856.75 (1666.076)		4946.07 (3855.792)	
	95% CI of Mean	3885.53, 5371.20		3234.62, 4478.87		3190.93, 6701.21	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set****Parameter (units): S-BMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	3508.78 (80.106)		3145.21 (53.816)		3666.72 (94.954)	
	95% CI of Geometric Mean	2970.16, 4145.09		2630.19, 3761.09		2569.84, 5231.76	
	Median	3474.58	-1.53	3040.70	-6.58	3935.19	4.83
	Q25, Q75	2175.00, 5089.29	-29.76, 22.61	2326.87, 4307.18	-34.39, 9.04	2580.95, 5767.74	-26.24, 39.31
	Min, Max	1019.4, 50279.3	-83.2, 812.1	1178.0, 8475.2	-55.3, 112.9	540.2, 14045.1	-81.4, 206.1
	Mean (SD)	4772.72 (6188.286)	9.33 (106.839)	3553.36 (1825.336)	-4.28 (39.475)	4744.37 (3375.233)	8.88 (64.412)
	95% CI of Mean	3307.97, 6237.47	-17.15, 35.81	2906.12, 4200.60	-19.02, 10.47	3247.87, 6240.87	-20.44, 38.21

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set****Parameter (units): S-BMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	3372.79 (72.896)		3070.67 (67.133)		4024.93 (100.961)	
	95% CI of Geometric Mean	2889.89, 3936.37		2473.46, 3812.08		2775.48, 5836.85	
	Median	3399.07	-7.22	2664.43	-5.90	3465.29	2.81
	Q25, Q75	2326.92, 5403.65	-34.90, 26.90	1900.00, 4637.46	-37.16, 60.41	2500.00, 8243.63	-27.23, 21.45
	Min, Max	596.7, 15367.1	-81.2, 191.2	943.4, 10480.0	-84.5, 188.0	883.8, 18613.9	-40.9, 388.4
	Mean (SD)	4133.82 (2845.968)	2.08 (52.856)	3674.68 (2290.800)	8.89 (66.286)	5609.49 (4872.018)	27.62 (96.618)
	95% CI of Mean	3460.19, 4807.46	-11.03, 15.18	2862.39, 4486.97	-15.87, 33.64	3449.35, 7769.62	-16.37, 71.60

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set**

Parameter (units): S-BMA (pg/mg creat)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	4281.83 (80.002)		4019.95 (80.326)		4512.26 (103.028)	
	95% CI of Geometric Mean	3625.16, 5057.46		3130.12, 5162.73		3094.70, 6579.15	
	Median	3702.03	18.33	4186.31	3.06	3857.54	10.02
	Q25, Q75	2733.33, 6628.57	-17.17, 45.66	2544.64, 6021.31	-23.34, 58.63	2699.03, 5683.45	-31.35, 73.73
	Min, Max	526.8, 17767.1	-61.0, 246.9	1079.8, 32096.1	-68.7, 1067.6	1150.4, 34119.1	-65.8, 326.5
	Mean (SD)	5433.49 (4051.817)	25.04 (60.445)	5337.68 (5581.989)	66.39 (216.435)	6927.35 (8445.438)	35.44 (92.148)
	95% CI of Mean	4474.44, 6392.55	10.06, 40.02	3358.39, 7316.98	-14.44, 147.21	3182.85, 10671.85	-6.51, 77.39

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set****Parameter (units): S-BMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	3702.94 (73.945)		3454.58 (79.741)		4373.14 (92.359)	
	95% CI of Geometric Mean	3167.05, 4329.49		2693.77, 4430.27		3087.20, 6194.72	
	Median	3603.69	4.31	3206.21	-2.72	4295.44	-5.51
	Q25, Q75	2505.45, 5880.00	-29.44, 30.09	2200.39, 5085.71	-34.62, 44.37	2314.81, 6957.45	-26.85, 69.18
	Min, Max	448.1, 15084.7	-71.6, 162.8	568.8, 28957.1	-90.3, 1117.7	1300.0, 34776.1	-68.4, 185.6
	Mean (SD)	4528.01 (2945.341)	7.95 (51.844)	4542.79 (4835.530)	39.28 (209.674)	6238.50 (7241.544)	27.48 (71.718)
	95% CI of Mean	3830.86, 5225.17	-4.90, 20.80	2828.18, 6257.40	-39.01, 117.58	3027.78, 9449.23	-5.17, 60.13

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set****Parameter (units): S-BMA (pg/mg creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	71	65	33	30	22	21
	Missing, n (%)	4 (5.3)	10 (13.3)	2 (5.7)	5 (14.3)	2 (8.3)	3 (12.5)
	Geometric Mean (CV%)	3683.79 (75.128)		3120.82 (78.430)		4769.75 (121.886)	
	95% CI of Geometric Mean	3144.33, 4315.80		2441.42, 3989.27		3124.33, 7281.73	
	Median	4204.55	-1.63	3596.64	-2.23	4244.50	23.18
	Q25, Q75	2374.62, 5339.45	-25.78, 25.55	2018.99, 4861.11	-38.53, 18.04	1981.48, 8211.14	-32.35, 90.58
	Min, Max	653.6, 15631.1	-87.7, 218.7	513.7, 15369.5	-83.6, 459.1	1433.1, 57142.9	-44.8, 272.4
	Mean (SD)	4548.33 (3099.890)	9.56 (55.898)	3869.68 (2746.860)	9.69 (97.681)	8218.38 (12297.096)	38.83 (81.559)
	95% CI of Mean	3814.59, 5282.06	-4.30, 23.41	2895.68, 4843.68	-26.79, 46.17	2766.15, 13670.61	1.70, 75.96

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set****Parameter (units): S-BMA (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	36		29		12	
	Missing, n (%)	4 (10.0)		5 (14.7)		1 (7.7)	
	Geometric Mean (CV%)	3869.88 (71.342)		3464.72 (41.597)		3607.21 (88.333)	
	95% CI of Geometric Mean	3114.90, 4807.84		2976.28, 4033.32		2226.44, 5844.29	
	Median	3838.02		3293.65		2878.15	
	Q25, Q75	2694.06, 6086.12		2662.16, 4339.18		1955.84, 4805.74	
	Min, Max	906.4, 16562.5		1688.4, 8363.6		1524.8, 15343.3	
	Mean (SD)	4694.28 (3129.774)		3749.87 (1602.676)		4898.52 (4664.643)	
	95% CI of Mean	3635.31, 5753.25		3140.24, 4359.51		1934.74, 7862.29	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set****Parameter (units): S-BMA (pg/mg creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	39	36	32	29	13	12
	Missing, n (%)	1 (2.5)	4 (10.0)	2 (5.9)	5 (14.7)	0	1 (7.7)
	Geometric Mean (CV%)	4331.22 (72.119)		3336.99 (78.964)		3706.69 (76.836)	
	95% CI of Geometric Mean	3511.59, 5342.14		2596.29, 4289.00		2455.97, 5594.36	
	Median	4464.86	0.54	3409.75	-7.04	3307.00	7.99
	Q25, Q75	3136.88, 6452.17	-23.40, 66.92	1908.30, 5915.73	-23.09, 35.99	2141.98, 4512.33	-27.55, 47.63
	Min, Max	658.1, 19429.5	-81.3, 230.6	590.6, 13978.5	-87.5, 408.5	1818.9, 19680.9	-78.4, 143.1
	Mean (SD)	5314.55 (3893.491)	31.27 (79.886)	4159.12 (2860.082)	26.76 (104.241)	4828.32 (4772.710)	16.83 (66.250)
	95% CI of Mean	4052.42, 6576.67	4.24, 58.31	3127.94, 5190.29	-12.89, 66.42	1944.19, 7712.44	-25.27, 58.92

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set****Parameter (units): S-BMA (pg/mg creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	35		30		11	
	Missing, n (%)	4 (10.3)		5 (14.3)		1 (8.3)	
	Geometric Mean (CV%)	3782.66 (71.162)		3464.07 (40.816)		2823.73 (73.883)	
	95% CI of Geometric Mean	3036.02, 4712.93		2991.77, 4010.92		1812.44, 4399.31	
	Median	3885.09		3329.61		2740.64	
	Q25, Q75	2666.67, 5474.86		2662.16, 4339.18		1701.49, 4450.00	
	Min, Max	906.4, 16562.5		1688.4, 8363.6		1422.2, 13742.5	
	Mean (SD)	4597.83 (3135.953)		3739.72 (1575.784)		3628.88 (3529.938)	
	95% CI of Mean	3520.59, 5675.07		3151.30, 4328.13		1257.43, 6000.33	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set**

Parameter (units): S-BMA (pg/mg creat)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	35	33	30	11	11
	Missing, n (%)	0	4 (10.3)	2 (5.7)	5 (14.3)	1 (8.3)	1 (8.3)
	Geometric Mean (CV%)	4008.75 (73.365)		4060.71 (108.148)		3574.67 (115.880)	
	95% CI of Geometric Mean	3240.58, 4959.00		2972.18, 5547.91		1923.22, 6644.19	
	Median	3986.93	3.49	3857.14	6.89	2813.95	41.90
	Q25, Q75	2527.47, 6031.39	-22.65, 57.69	2412.43, 5635.91	-20.83, 46.51	1937.50, 3888.89	-22.46, 107.66
	Min, Max	795.6, 26346.2	-57.9, 334.4	951.1, 57291.7	-65.4, 1639.5	1505.1, 44468.5	-58.4, 223.6
	Mean (SD)	5024.49 (4310.680)	26.44 (76.357)	6562.53 (10046.297)	99.46 (313.589)	6773.34 (12563.512)	47.92 (82.712)
	95% CI of Mean	3627.12, 6421.85	0.21, 52.68	3000.26, 10124.80	-17.64, 216.56	-1666.95, 15213.62	-7.65, 103.49

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set****Parameter (units): S-BMA (pg/mg creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	43		29		9	
	Missing, n (%)	4 (8.5)		3 (9.4)		0	
	Geometric Mean (CV%)	3676.09 (68.386)		3474.68 (41.556)		2978.23 (81.476)	
	95% CI of Geometric Mean	3038.07, 4448.09		2985.24, 4044.36		1720.92, 5154.11	
	Median	3790.95		3365.57		2740.64	
	Q25, Q75	2666.67, 5474.86		2662.16, 4339.18		1816.57, 4450.00	
	Min, Max	906.4, 16562.5		1688.4, 8363.6		1422.2, 13742.5	
	Mean (SD)	4415.22 (2921.555)		3759.36 (1599.932)		3923.86 (3866.158)	
	95% CI of Mean	3516.09, 5314.35		3150.78, 4367.95		952.06, 6895.66	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set**

Parameter (units): S-BMA (pg/mg creat)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	43	32	29	9	9
	Missing, n (%)	0	4 (8.5)	0	3 (9.4)	0	
	Geometric Mean (CV%)	3688.05 (79.646)		3441.11 (128.454)		3833.64 (89.736)	
	95% CI of Geometric Mean	3002.09, 4530.74		2410.57, 4912.19		2123.44, 6921.21	
	Median	3561.95	15.20	3613.22	-5.83	3863.37	35.32
	Q25, Q75	2210.20, 5248.76	-36.06, 66.05	2167.11, 5477.42	-46.16, 58.34	2288.46, 5196.08	11.31, 50.14
	Min, Max	937.5, 29511.4	-78.4, 387.5	266.8, 59729.7	-92.4, 2072.9	1333.3, 17806.8	-26.6, 82.1
	Mean (SD)	4956.42 (5493.594)	28.91 (92.735)	5932.50 (10304.310)	88.68 (391.190)	5159.73 (5042.456)	33.18 (34.625)
	95% CI of Mean	3343.44, 6569.41	0.37, 57.46	2217.39, 9647.60	-60.12, 237.49	1283.75, 9035.71	6.56, 59.80

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set**

Parameter (units): S-BMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	67	30	21
	Missing, n (%)	8 (10.7)	5 (14.3)	3 (12.5)
	Geometric Mean (CV%)	6473.58 (63.887)	5627.56 (44.624)	6324.81 (63.313)
	95% CI of Geometric Mean	5612.66, 7466.56	4799.69, 6598.21	4855.93, 8238.01
	Median	6552.00	5703.28	6116.89
	Q25, Q75	4540.50, 9668.88	3910.04, 7318.18	4358.48, 10205.23
	Min, Max	1186.1, 19647.1	1957.0, 12410.8	2122.9, 16559.4
	Mean (SD)	7586.39 (4353.164)	6119.16 (2493.949)	7388.03 (4192.732)
	95% CI of Mean	6524.56, 8648.21	5187.90, 7050.42	5479.52, 9296.54

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set**

Parameter (units): S-BMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	Geometric Mean (CV%)	5774.06 (76.067)	5065.86 (54.539)	5922.60 (89.384)
	95% CI of Geometric Mean	4920.66, 6775.46	4227.37, 6070.64	4216.57, 8318.88
	Median	5746.50	5428.50	5954.32
	Q25, Q75	3969.24, 8807.58	4104.84, 7224.08	4184.07, 11301.22
	Min, Max	1350.0, 70200.0	1361.1, 12626.0	784.5, 14554.8
	Mean (SD)	7540.64 (8589.328)	5666.26 (2562.880)	7332.98 (4101.935)
	95% CI of Mean	5507.57, 9573.71	4757.50, 6575.03	5514.28, 9151.68

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set**

Parameter (units): S-BMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	Geometric Mean (CV%)	5537.76 (77.541)	5019.54 (79.514)	6649.75 (82.593)
	95% CI of Geometric Mean	4707.62, 6514.29	3916.27, 6433.60	4829.94, 9155.21
	Median	5782.14	5442.60	6046.47
	Q25, Q75	3386.55, 9067.80	3221.97, 7670.52	4758.50, 13531.50
	Min, Max	1215.4, 20918.5	1206.0, 16728.0	1581.3, 19664.8
	Mean (SD)	6918.68 (4787.367)	6247.44 (4081.570)	8340.17 (5482.612)
	95% CI of Mean	5785.53, 8051.84	4800.17, 7694.71	5909.31, 10771.03

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set**

Parameter (units): S-BMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	Geometric Mean (CV%)	7004.72 (85.593)	6501.21 (89.854)	6967.74 (86.305)
	95% CI of Geometric Mean	5877.33, 8348.35	4949.04, 8540.19	5005.25, 9699.69
	Median	7180.14	6099.60	6538.12
	Q25, Q75	4612.74, 10156.47	3961.68, 8523.97	4729.48, 8153.50
	Min, Max	739.1, 40323.4	1511.8, 66752.7	1549.9, 33577.5
	Mean (SD)	9071.60 (7201.056)	9313.31 (11770.216)	9339.15 (8555.872)
	95% CI of Mean	7367.14, 10776.07	5139.77, 13486.85	5545.68, 13132.61

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set**

Parameter (units): S-BMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	Geometric Mean (CV%)	6107.25 (70.317)	5508.66 (77.178)	6856.71 (76.186)
	95% CI of Geometric Mean	5256.42, 7095.81	4322.94, 7019.60	5079.79, 9255.18
	Median	5906.40	5575.20	7656.86
	Q25, Q75	4047.68, 9543.24	3728.76, 8509.89	4565.60, 9827.68
	Min, Max	892.6, 22628.1	978.4, 35447.2	1868.2, 31408.4
	Mean (SD)	7398.28 (4790.924)	6968.81 (6009.705)	8549.72 (6548.782)
	95% CI of Mean	6264.28, 8532.28	4837.86, 9099.77	5646.15, 11453.29

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set**

Parameter (units): S-BMA (ng)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	71	33	22
	Missing, n (%)	4 (5.3)	2 (5.7)	2 (8.3)
	Geometric Mean (CV%)	6249.36 (72.816)	5115.74 (86.138)	7954.14 (92.590)
	95% CI of Geometric Mean	5355.36, 7292.61	3928.11, 6662.44	5611.56, 11274.65
	Median	6376.70	5543.93	7874.00
	Q25, Q75	3829.93, 10000.51	4008.30, 8163.54	4668.32, 12869.90
	Min, Max	1146.1, 23055.2	614.7, 31324.8	2189.6, 43060.4
	Mean (SD)	7620.12 (4905.618)	6532.90 (5301.953)	10895.37 (10101.861)
	95% CI of Mean	6458.98, 8781.27	4652.90, 8412.89	6416.45, 15374.29

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set**

Parameter (units): S-BMA (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	37	29	12
	Missing, n (%)	3 (7.5)	5 (14.7)	1 (7.7)
	Geometric Mean (CV%)	6373.76 (69.863)	5680.77 (45.306)	5651.15 (66.984)
	95% CI of Geometric Mean	5165.40, 7864.80	4819.79, 6695.55	3838.33, 8320.16
	Median	6210.54	5895.48	5534.57
	Q25, Q75	4540.50, 9915.18	3910.04, 7318.18	3480.47, 7624.07
	Min, Max	1186.1, 19647.1	1957.0, 12410.8	2571.8, 16559.4
	Mean (SD)	7586.45 (4407.856)	6185.79 (2518.848)	6747.75 (4489.998)
	95% CI of Mean	6116.79, 9056.11	5227.66, 7143.91	3894.94, 9600.56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set**

Parameter (units): S-BMA (ng)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Day 30	n	39	32	13
	Missing, n (%)	1 (2.5)	2 (5.9)	0
	Geometric Mean (CV%)	6963.00 (82.035)	5573.48 (78.686)	6088.37 (64.497)
	95% CI of Geometric Mean	5518.30, 8785.92	4339.41, 7158.50	4263.07, 8695.20
	Median	6926.48	5444.77	6988.60
	Q25, Q75	4722.26, 8925.30	3492.37, 10039.88	3669.11, 7859.57
	Min, Max	1154.6, 45458.0	1517.4, 27305.2	2665.3, 17105.1
	Mean (SD)	9109.73 (8210.233)	7052.11 (5387.288)	7158.68 (4410.773)
	95% CI of Mean	6448.27, 11771.18	5109.78, 8994.44	4493.27, 9824.08

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set**

Parameter (units): S-BMA (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	37	30	11
	Missing, n (%)	2 (5.1)	5 (14.3)	1 (8.3)
	Geometric Mean (CV%)	6510.25 (64.072)	5642.57 (44.628)	4571.73 (62.626)
	95% CI of Geometric Mean	5353.95, 7916.27	4812.44, 6615.90	3106.36, 6728.36
	Median	6663.06	5875.14	4358.48
	Q25, Q75	4540.50, 9915.18	3910.04, 7318.18	2640.60, 7180.52
	Min, Max	1186.1, 19647.1	1957.0, 12410.8	2122.9, 14384.0
	Mean (SD)	7556.72 (3993.877)	6134.25 (2491.081)	5370.76 (3542.884)
	95% CI of Mean	6225.09, 8888.35	5204.06, 7064.44	2990.61, 7750.91

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set**

Parameter (units): S-BMA (ng)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Day 60	n	39	33	11
	Missing, n (%)	0	2 (5.7)	1 (8.3)
	Geometric Mean (CV%)	6511.61 (66.780)	6804.92 (133.648)	5970.77 (77.514)
	95% CI of Geometric Mean	5348.06, 7928.30	4752.70, 9743.28	3766.14, 9465.96
	Median	6344.95	6427.08	5506.04
	Q25, Q75	4549.40, 8339.84	3511.66, 11969.10	3822.72, 6718.85
	Min, Max	1934.8, 32915.7	977.4, 148335.0	2418.3, 35670.0
	Mean (SD)	7921.50 (6042.690)	12887.76 (25411.895)	8038.56 (9309.265)
	95% CI of Mean	5962.68, 9880.31	3877.09, 21898.43	1784.51, 14292.61

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set**

Parameter (units): S-BMA (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	45	29	9
	Missing, n (%)	2 (4.3)	3 (9.4)	0
	Geometric Mean (CV%)	6208.48 (64.208)	5684.87 (45.264)	4830.39 (66.700)
	95% CI of Geometric Mean	5203.87, 7407.03	4823.95, 6699.44	3030.15, 7700.16
	Median	6552.00	5895.48	4358.48
	Q25, Q75	4540.50, 9668.88	3910.04, 7318.18	3025.20, 7180.52
	Min, Max	1186.1, 19647.1	1957.0, 12410.8	2122.9, 14384.0
	Mean (SD)	7212.99 (3821.181)	6189.10 (2516.672)	5728.25 (3813.806)
	95% CI of Mean	6064.98, 8361.00	5231.81, 7146.40	2796.70, 8659.81

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.1 Descriptive Statistics of S-BMA in 24-hour Urine Collection - PP Set**

Parameter (units): S-BMA (ng)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Day 90	n	47	32	9
	Geometric Mean (CV%)	6188.20 (76.814)	5713.31 (138.057)	6562.28 (85.564)
	95% CI of Geometric Mean	5066.74, 7557.89	3937.00, 8291.07	3712.18, 11600.59
	Median	6695.78	5779.26	5097.12
	Q25, Q75	3764.48, 9000.48	3465.23, 9532.79	3735.84, 11014.20
	Min, Max	1698.8, 38966.4	471.3, 104533.0	2723.4, 19096.0
	Mean (SD)	7907.65 (6813.243)	10201.37 (18094.372)	8413.10 (6392.538)
	95% CI of Mean	5907.20, 9908.10	3677.65, 16725.09	3499.36, 13326.85

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	69		36		36	
	Missing, n (%)	11 (13.8)		5 (12.2)		3 (7.7)	
	Geometric Mean (CV%)	3877.89 (66.177)		3532.23 (42.853)		3741.63 (61.064)	
	95% CI of Geometric Mean	3355.21, 4482.00		3074.07, 4058.68		3092.71, 4526.71	
	Median	3885.09		3382.43		3443.96	
	Q25, Q75	2666.67, 5773.52		2653.59, 4663.30		2797.77, 4778.28	
	Min, Max	906.4, 16562.5		1688.4, 8363.6		1422.2, 15343.3	
	Mean (SD)	4627.54 (2939.974)		3838.58 (1646.180)		4443.56 (3137.686)	
	95% CI of Mean	3921.28, 5333.80		3281.59, 4395.57		3381.92, 5505.21	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	3554.81 (79.043)		3129.04 (54.210)		3808.57 (84.796)	
	95% CI of Geometric Mean	3028.32, 4172.83		2654.31, 3688.68		2979.76, 4867.91	
	Median	3474.58	-0.40	3040.70	-11.19	3894.93	3.52
	Q25, Q75	2208.46, 5089.29	-28.79, 22.61	2220.42, 4437.37	-33.08, 6.91	2580.95, 6706.67	-14.30, 37.94
	Min, Max	1019.4, 50279.3	-83.2, 812.1	1178.0, 8475.2	-55.3, 112.9	540.2, 14045.1	-81.4, 206.1
	Mean (SD)	4789.83 (6051.325)	9.17 (103.730)	3537.06 (1788.005)	-4.89 (37.914)	4780.79 (3131.073)	17.46 (66.234)
	95% CI of Mean	3397.54, 6182.12	-15.75, 34.10	2957.46, 4116.67	-17.72, 7.94	3736.83, 5824.74	-4.96, 39.87

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	3373.78 (71.999)		3102.20 (63.820)		3877.05 (95.267)	
	95% CI of Geometric Mean	2907.64, 3914.65		2566.72, 3749.40		2965.75, 5068.38	
	Median	3399.07	-11.16	3320.00	-5.43	3597.25	0.00
	Q25, Q75	2326.92, 5403.65	-32.86, 23.55	1900.00, 5030.53	-36.90, 44.54	2435.72, 7693.32	-23.66, 32.05
	Min, Max	596.7, 15367.1	-81.2, 191.2	943.4, 10480.0	-84.5, 188.0	549.0, 18613.9	-80.0, 388.4
	Mean (SD)	4118.69 (2802.446)	0.81 (51.577)	3657.63 (2170.912)	7.35 (61.687)	5214.82 (4184.223)	25.10 (84.940)
	95% CI of Mean	3473.90, 4763.48	-11.59, 13.20	2953.90, 4361.37	-13.52, 28.23	3819.72, 6609.91	-3.64, 53.84

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	4281.62 (78.360)		3923.93 (79.263)		4323.11 (83.868)	
	95% CI of Geometric Mean	3651.50, 5020.47		3129.14, 4920.61		3389.38, 5514.08	
	Median	3890.78	16.41	3938.27	1.89	3919.64	12.47
	Q25, Q75	2733.33, 6628.57	-14.36, 45.37	2430.13, 6082.64	-25.03, 60.19	2699.03, 5671.49	-14.27, 41.03
	Min, Max	526.8, 17767.1	-61.0, 246.9	1079.8, 32096.1	-68.7, 1067.6	1150.4, 34119.1	-65.8, 326.5
	Mean (SD)	5393.98 (3968.834)	23.63 (58.929)	5167.65 (5255.709)	57.48 (199.373)	5996.65 (6747.831)	31.33 (80.936)
	95% CI of Mean	4480.83, 6307.13	9.47, 37.79	3463.94, 6871.36	-9.98, 124.94	3746.80, 8246.49	3.94, 58.72

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	3738.83 (73.733)		3462.59 (74.605)		4270.52 (79.123)	
	95% CI of Geometric Mean	3212.90, 4350.86		2790.95, 4295.85		3384.68, 5388.18	
	Median	3625.00	4.31	3533.06	-1.22	4234.94	0.00
	Q25, Q75	2505.45, 5896.95	-28.12, 28.30	2200.39, 5085.71	-28.98, 36.81	2604.97, 5936.94	-21.56, 52.26
	Min, Max	448.1, 15084.7	-71.6, 162.8	568.8, 28957.1	-90.3, 1117.7	1300.0, 34776.1	-68.4, 366.7
	Mean (SD)	4565.95 (2940.321)	7.86 (50.538)	4433.92 (4493.495)	33.73 (191.611)	5683.44 (5958.686)	30.13 (81.121)
	95% CI of Mean	3889.44, 5242.46	-4.29, 20.00	2977.30, 5890.55	-31.11, 98.56	3696.71, 7670.17	2.68, 57.58

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	3690.88 (74.556)		3209.51 (76.318)		4138.22 (97.863)	
	95% CI of Geometric Mean	3167.35, 4300.95		2576.69, 3997.75		3148.70, 5438.71	
	Median	4204.55	-1.84	3596.64	-1.82	3894.93	1.27
	Q25, Q75	2374.62, 5339.45	-25.53, 25.15	2018.99, 4939.76	-38.44, 19.79	1981.48, 6750.39	-24.27, 60.19
	Min, Max	653.6, 15631.1	-87.7, 218.7	513.7, 15369.5	-83.6, 459.1	1433.1, 57142.9	-44.8, 272.4
	Mean (SD)	4546.38 (3072.672)	8.50 (54.564)	3952.20 (2721.722)	12.24 (93.704)	6437.83 (9723.298)	23.08 (68.022)
	95% CI of Mean	3839.42, 5253.35	-4.61, 21.62	3069.92, 4834.49	-19.47, 43.95	3195.92, 9679.74	0.06, 46.10

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	4527.53 (94.286)		3494.21 (77.420)		4093.69 (81.422)	
	95% CI of Geometric Mean	3768.52, 5439.40		2798.16, 4363.41		3227.37, 5192.55	
	Median	4562.09	3.37	3779.34	-4.01	3980.95	0.00
	Q25, Q75	2877.36, 7016.27	-13.40, 71.77	1918.77, 6213.02	-25.58, 39.37	2224.49, 5640.29	-15.93, 46.16
	Min, Max	500.0, 72463.8	-81.3, 459.1	590.6, 13978.5	-87.5, 408.5	769.8, 19680.9	-78.4, 407.7
	Mean (SD)	6503.39 (8911.336)	37.40 (91.341)	4320.19 (2841.234)	26.46 (97.527)	5331.28 (4521.838)	31.40 (96.505)
	95% CI of Mean	4453.07, 8553.70	15.46, 59.35	3399.16, 5241.21	-6.54, 59.46	3823.62, 6838.94	-1.26, 64.06

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	4576.32 (78.044)		3987.24 (103.439)		4005.22 (72.914)	
	95% CI of Geometric Mean	3904.83, 5363.29		3024.07, 5257.17		3221.65, 4979.36	
	Median	4036.57	22.31	3857.14	0.70	3774.73	0.00
	Q25, Q75	2849.58, 6204.08	-9.12, 75.50	2401.00, 6049.72	-17.53, 41.30	2672.41, 5023.77	-14.86, 36.32
	Min, Max	795.6, 29338.8	-57.9, 334.4	951.1, 57291.7	-65.4, 1639.5	1505.1, 44468.5	-58.4, 223.6
	Mean (SD)	5969.76 (5438.054)	43.56 (85.855)	6233.01 (9303.580)	82.20 (288.307)	5415.40 (7159.225)	17.51 (57.353)
	95% CI of Mean	4718.57, 7220.94	22.93, 64.19	3217.13, 9248.89	-15.36, 179.75	3028.39, 7802.41	-1.90, 36.92

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (pg/mg creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	75	69	39	36	37	36
	Missing, n (%)	5 (6.3)	11 (13.8)	2 (4.9)	5 (12.2)	2 (5.1)	3 (7.7)
	Geometric Mean (CV%)	3950.03 (84.821)		3653.40 (117.654)		3544.86 (72.741)	
	95% CI of Geometric Mean	3334.54, 4679.12		2700.65, 4942.25		2852.55, 4405.19	
	Median	3832.06	15.20	3784.25	2.68	3667.51	0.00
	Q25, Q75	2446.66, 5776.81	-31.24, 78.18	2509.58, 6057.23	-43.64, 53.70	2288.46, 5196.08	-23.51, 32.45
	Min, Max	343.8, 29511.4	-95.7, 452.4	266.8, 59729.7	-92.4, 2072.9	843.1, 17806.8	-85.1, 221.8
	Mean (SD)	5236.58 (4964.783)	36.09 (101.005)	5883.14 (9424.174)	77.72 (351.027)	4393.08 (3305.478)	8.98 (60.546)
	95% CI of Mean	4094.29, 6378.88	11.82, 60.36	2828.18, 8938.11	-41.06, 196.49	3290.97, 5495.18	-11.51, 29.47

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	71	36	36
	Missing, n (%)	9 (11.3)	5 (12.2)	3 (7.7)
	Geometric Mean (CV%)	6513.00 (64.336)	5645.41 (42.341)	6123.05 (54.154)
	95% CI of Geometric Mean	5666.09, 7486.50	4920.67, 6476.90	5157.62, 7269.20
	Median	6225.96	5703.28	6174.32
	Q25, Q75	4540.50, 9668.88	4091.87, 7307.53	4250.89, 8438.08
	Min, Max	1186.1, 20252.9	1957.0, 12410.8	2122.9, 16559.4
	Mean (SD)	7666.59 (4521.562)	6098.63 (2403.425)	6915.00 (3492.299)
	95% CI of Mean	6596.35, 8736.83	5285.42, 6911.83	5733.37, 8096.62

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 1	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	Geometric Mean (CV%)	5834.72 (76.291)	5035.44 (53.382)	6338.14 (78.876)
	95% CI of Geometric Mean	4992.81, 6818.60	4280.98, 5922.85	5026.32, 7992.32
	Median	5719.35	5428.50	5895.30
	Q25, Q75	3969.24, 8807.58	3917.16, 7224.08	4291.98, 11285.82
	Min, Max	1350.0, 70200.0	1361.1, 12626.0	784.5, 26316.3
	Mean (SD)	7627.81 (8542.361)	5624.77 (2562.052)	7756.27 (4927.193)
	95% CI of Mean	5662.38, 9593.23	4794.24, 6455.30	6113.46, 9399.08

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 2	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	Geometric Mean (CV%)	5522.21 (77.198)	5063.74 (73.391)	6477.51 (78.395)
	95% CI of Geometric Mean	4718.40, 6462.96	4093.17, 6264.46	5142.61, 8158.91
	Median	5713.07	5442.60	6044.94
	Q25, Q75	3386.55, 9067.80	3261.44, 7670.52	4392.80, 10856.20
	Min, Max	1215.4, 20918.5	1206.0, 16728.0	1439.2, 28560.6
	Mean (SD)	6899.66 (4785.919)	6154.67 (3844.542)	8107.27 (5778.098)
	95% CI of Mean	5798.51, 8000.80	4908.41, 7400.93	6180.75, 10033.79

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 3	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	Geometric Mean (CV%)	6994.93 (84.284)	6315.05 (85.904)	6877.79 (72.082)
	95% CI of Geometric Mean	5909.89, 8279.18	4962.65, 8035.99	5543.48, 8533.26
	Median	7157.50	5777.77	5927.80
	Q25, Q75	4612.74, 10156.47	3398.40, 10072.76	4745.34, 7768.25
	Min, Max	739.1, 40323.4	1511.8, 66752.7	1549.9, 33577.5
	Mean (SD)	9018.58 (7106.109)	8860.30 (10964.724)	8757.06 (7763.353)
	95% CI of Mean	7383.61, 10653.55	5305.94, 12414.66	6168.63, 11345.50

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 4	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	Geometric Mean (CV%)	6139.26 (71.031)	5558.16 (71.245)	6842.91 (69.693)
	95% CI of Geometric Mean	5299.72, 7111.79	4515.75, 6841.18	5547.94, 8440.13
	Median	5906.40	5575.20	7268.04
	Q25, Q75	4047.68, 9543.24	4031.42, 8509.89	4641.00, 8501.57
	Min, Max	892.6, 22628.1	978.4, 35447.2	1868.2, 38142.4
	Mean (SD)	7473.38 (4924.732)	6844.21 (5582.806)	8508.66 (7246.899)
	95% CI of Mean	6340.30, 8606.46	5034.46, 8653.95	6092.42, 10924.91

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 5	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	Geometric Mean (CV%)	6254.08 (73.459)	5292.06 (81.749)	7018.64 (79.174)
	95% CI of Geometric Mean	5376.79, 7274.50	4196.71, 6673.30	5562.11, 8856.58
	Median	6376.70	5543.93	6682.44
	Q25, Q75	3829.93, 10000.51	4008.30, 8163.54	4655.25, 10088.94
	Min, Max	1146.1, 23055.2	614.7, 31324.8	2189.6, 43060.4
	Mean (SD)	7665.32 (5034.991)	6652.70 (5175.162)	9164.45 (8337.459)
	95% CI of Mean	6506.87, 8823.77	4975.10, 8330.30	6384.60, 11944.30

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	Geometric Mean (CV%)	7334.24 (100.177)	5537.10 (71.428)	6736.65 (68.054)
	95% CI of Geometric Mean	6054.22, 8884.89	4496.69, 6818.24	5484.21, 8275.10
	Median	6926.48	5442.60	7308.40
	Q25, Q75	4373.67, 11045.92	3669.12, 8117.97	4443.93, 9545.97
	Min, Max	1053.4, 154000.0	1517.4, 27305.2	1419.7, 31038.0
	Mean (SD)	11448.73 (19153.454)	6797.77 (4946.361)	8139.52 (5710.884)
	95% CI of Mean	7041.92, 15855.55	5194.34, 8401.20	6235.41, 10043.62

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	Geometric Mean (CV%)	7330.50 (78.183)	6496.74 (122.230)	6782.19 (66.640)
	95% CI of Geometric Mean	6253.47, 8593.02	4765.53, 8856.87	5541.04, 8301.34
	Median	6539.76	6292.76	6407.82
	Q25, Q75	4549.40, 10593.54	3455.82, 10480.80	4796.21, 8210.60
	Min, Max	1934.8, 53995.5	977.4, 148335.0	2418.3, 64871.3
	Mean (SD)	9657.51 (9320.090)	11776.79 (23492.581)	8852.42 (10853.324)
	95% CI of Mean	7513.15, 11801.87	4161.37, 19392.20	5233.73, 12471.10

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.17.2 Descriptive Statistics of S-BMA in 24-hour Urine Collection - FAS****Parameter (units): S-BMA (ng)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	75	39	37
	Missing, n (%)	5 (6.3)	2 (4.9)	2 (5.1)
	Geometric Mean (CV%)	6594.59 (86.419)	5776.22 (123.140)	5786.22 (67.477)
	95% CI of Geometric Mean	5553.42, 7830.97	4230.63, 7886.47	4717.33, 7097.30
	Median	7053.06	5485.74	5895.30
	Q25, Q75	3928.92, 10038.60	3511.66, 8934.25	4143.30, 8875.50
	Min, Max	775.4, 38966.4	471.3, 104533.0	1218.3, 19096.0
	Mean (SD)	8650.96 (7097.886)	9658.78 (16522.760)	6864.68 (4095.535)
	95% CI of Mean	7017.88, 10284.04	4302.72, 15014.85	5499.16, 8230.20

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set****Parameter (units): NEQ (mg/g creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		30		21	
	Missing, n (%)	8 (10.7)		5 (14.3)		3 (12.5)	
	BLOQ, n(%)	7 (10.4)		3 (10.0)		0	
	Geometric Mean (CV%)	7.52 (58.077)		8.30 (46.665)		7.68 (52.989)	
	95% CI of Geometric Mean	6.59, 8.58		7.03, 9.80		6.12, 9.64	
	Median	7.86		8.34		7.79	
	Q25, Q75	6.31, 9.94		6.26, 11.25		5.81, 9.18	
	Min, Max	0.5, 33.6		3.1, 21.7		2.8, 28.8	
	Mean (SD)	8.43 (4.200)		9.13 (4.196)		8.73 (5.361)	
	95% CI of Mean	7.40, 9.46		7.56, 10.70		6.28, 11.17	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set**

Parameter (units): NEQ (mg/g creat)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	10 (13.7)		3 (8.8)		5 (22.7)	
	Geometric Mean (CV%)	6.40 (57.645)		7.90 (56.181)		4.75 (54.862)	
	95% CI of Geometric Mean	5.65, 7.26		6.58, 9.49		3.78, 5.96	
	Median	6.87	-16.18	7.87	-2.75	4.71	-37.45
	Q25, Q75	5.52, 8.77	-23.22, -3.93	5.88, 12.24	-11.68, 8.61	3.58, 6.12	-41.45, -29.95
	Min, Max	0.5, 19.2	-43.9, 63.4	2.0, 20.9	-32.4, 30.7	1.9, 17.3	-75.8, -10.0
	Mean (SD)	7.16 (3.029)	-12.71 (18.970)	8.91 (4.246)	-1.66 (13.998)	5.43 (3.330)	-37.51 (13.877)
	95% CI of Mean	6.44, 7.87	-17.35, -8.08	7.42, 10.40	-6.90, 3.57	3.95, 6.91	-43.83, -31.19

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set****Parameter (units): NEQ (mg/g creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	9 (12.3)		3 (8.8)		14 (63.6)	
	Geometric Mean (CV%)	5.57 (62.505)		7.57 (61.346)		2.15 (55.215)	
	95% CI of Geometric Mean	4.87, 6.37		6.21, 9.22		1.70, 2.71	
	Median	6.06	-25.13	7.69	-0.99	2.01	-73.69
	Q25, Q75	4.63, 8.54	-38.06, -6.46	5.43, 12.44	-14.28, 4.15	1.66, 3.09	-76.54, -68.56
	Min, Max	0.6, 15.4	-71.5, 44.5	1.6, 20.5	-52.5, 27.2	0.7, 5.9	-82.3, -41.4
	Mean (SD)	6.35 (2.915)	-21.27 (25.131)	8.68 (4.352)	-5.06 (18.499)	2.43 (1.252)	-71.92 (8.472)
	95% CI of Mean	5.67, 7.04	-27.40, -15.13	7.16, 10.21	-11.97, 1.86	1.87, 2.99	-75.78, -68.06

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set****Parameter (units): NEQ (mg/g creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	8 (11.0)		3 (8.8)		22 (100.0)	
	Geometric Mean (CV%)	5.93 (64.618)		7.74 (57.454)		0.91 (65.274)	
	95% CI of Geometric Mean	5.16, 6.81		6.42, 9.33		0.69, 1.18	
	Median	6.28	-18.31	8.02	0.03	0.93	-89.08
	Q25, Q75	4.95, 8.43	-36.44, 1.27	5.60, 11.45	-17.49, 10.03	0.73, 1.38	-90.74, -85.41
	Min, Max	0.5, 19.0	-66.1, 52.2	1.5, 19.3	-50.9, 27.7	0.3, 2.1	-94.5, -78.0
	Mean (SD)	6.77 (3.136)	-14.63 (29.256)	8.73 (4.096)	-2.97 (19.002)	1.06 (0.578)	-87.88 (4.419)
	95% CI of Mean	6.03, 7.51	-21.77, -7.49	7.30, 10.17	-10.07, 4.13	0.80, 1.32	-89.90, -85.87

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set****Parameter (units): NEQ (mg/g creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	9 (12.3)		3 (8.8)		22 (100.0)	
	Geometric Mean (CV%)	6.45 (68.575)		7.93 (58.795)		0.42 (69.193)	
	95% CI of Geometric Mean	5.57, 7.46		6.55, 9.59		0.32, 0.56	
	Median	7.20	-11.34	7.70	1.71	0.45	-94.41
	Q25, Q75	5.10, 8.97	-28.07, 9.73	5.79, 12.99	-10.19, 15.12	0.30, 0.60	-96.44, -92.67
	Min, Max	0.3, 18.2	-58.4, 75.3	1.7, 19.5	-54.0, 45.8	0.1, 1.1	-97.4, -88.5
	Mean (SD)	7.39 (3.331)	-7.05 (30.573)	9.00 (4.282)	0.25 (22.076)	0.50 (0.286)	-94.20 (2.537)
	95% CI of Mean	6.60, 8.17	-14.51, 0.42	7.50, 10.49	-8.00, 8.50	0.37, 0.63	-95.36, -93.04

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set****Parameter (units): NEQ (mg/g creat)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	67	34	30	22	21
	Missing, n (%)	2 (2.7)	8 (10.7)	1 (2.9)	5 (14.3)	2 (8.3)	3 (12.5)
	BLOQ, n(%)	11 (15.1)		4 (11.8)		21 (95.5)	
	Geometric Mean (CV%)	6.74 (75.334)		8.55 (53.053)		0.23 (164.750)	
	95% CI of Geometric Mean	5.76, 7.89		7.18, 10.18		0.14, 0.39	
	Median	7.23	-6.27	8.37	6.58	0.21	-97.56
	Q25, Q75	5.45, 9.41	-23.11, 17.25	6.14, 12.83	-0.08, 16.24	0.13, 0.32	-98.43, -96.23
	Min, Max	0.2, 20.5	-66.0, 108.1	2.1, 21.7	-32.0, 35.7	0.0, 12.6	-99.0, -4.2
	Mean (SD)	7.82 (3.668)	-1.77 (34.302)	9.55 (4.408)	6.02 (17.065)	0.81 (2.649)	-92.74 (20.338)
	95% CI of Mean	6.96, 8.68	-10.14, 6.60	8.01, 11.09	-0.36, 12.40	-0.37, 1.99	-102.01, -83.48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set****Parameter (units): NEQ (mg/g creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		29		12	
	Missing, n (%)	3 (7.5)		5 (14.7)		1 (7.7)	
	BLOQ, n(%)	4 (10.8)		4 (13.8)		0	
	Geometric Mean (CV%)	7.59 (67.879)		8.03 (46.884)		7.91 (63.523)	
	95% CI of Geometric Mean	6.18, 9.32		6.77, 9.52		5.46, 11.45	
	Median	7.91		8.31		6.99	
	Q25, Q75	6.27, 9.82		5.78, 11.21		5.81, 11.07	
	Min, Max	0.5, 33.6		3.1, 21.7		2.8, 28.8	
	Mean (SD)	8.75 (5.075)		8.85 (4.164)		9.39 (6.818)	
	95% CI of Mean	7.06, 10.45		7.26, 10.44		5.06, 13.73	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set****Parameter (units): NEQ (mg/g creat)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	37	33	29	13	12
	Missing, n (%)	0	3 (7.5)	1 (2.9)	5 (14.7)	0	1 (7.7)
	BLOQ, n(%)	5 (12.5)		5 (15.2)		4 (30.8)	
	Geometric Mean (CV%)	7.64 (80.453)		7.69 (68.525)		1.32 (471.117)	
	95% CI of Geometric Mean	6.09, 9.58		6.17, 9.59		0.45, 3.85	
	Median	7.99	-0.15	8.09	5.17	3.20	-78.89
	Q25, Q75	6.80, 10.83	-20.52, 31.98	5.43, 13.41	-18.91, 19.62	0.42, 6.33	-95.30, -39.18
	Min, Max	0.3, 20.3	-62.7, 152.2	1.9, 20.7	-52.3, 58.4	0.1, 8.1	-99.5, -13.7
	Mean (SD)	9.00 (4.417)	6.60 (43.706)	9.09 (5.026)	2.77 (27.722)	3.26 (3.023)	-66.95 (29.963)
	95% CI of Mean	7.59, 10.42	-7.98, 21.18	7.31, 10.88	-7.78, 13.32	1.42, 5.09	-86.00, -47.91

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set**

Parameter (units): NEQ (mg/g creat)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	35		30		11	
	Missing, n (%)	4 (10.3)		5 (14.3)		1 (8.3)	
	BLOQ, n(%)	5 (14.3)		4 (13.3)		0	
	Geometric Mean (CV%)	7.45 (73.275)		8.00 (46.051)		6.40 (50.792)	
	95% CI of Geometric Mean	5.94, 9.34		6.78, 9.42		4.63, 8.83	
	Median	8.25		8.14		6.19	
	Q25, Q75	6.31, 9.81		5.78, 11.21		5.51, 8.50	
	Min, Max	0.5, 33.6		3.1, 21.7		2.8, 13.2	
	Mean (SD)	8.72 (5.195)		8.79 (4.104)		7.08 (3.345)	
	95% CI of Mean	6.93, 10.51		7.25, 10.33		4.82, 9.33	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set****Parameter (units): NEQ (mg/g creat)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	35	34	30	11	11
	Missing, n (%)	0	4 (10.3)	1 (2.9)	5 (14.3)	1 (8.3)	1 (8.3)
	BLOQ, n(%)	6 (15.4)		4 (11.8)		5 (45.5)	
	Geometric Mean (CV%)	6.36 (94.092)		7.05 (73.099)		1.03 (586.123)	
	95% CI of Geometric Mean	4.91, 8.24		5.61, 8.87		0.28, 3.65	
	Median	7.53	-8.05	6.76	-8.89	1.60	-64.67
	Q25, Q75	4.04, 10.28	-45.58, 18.93	5.21, 11.54	-23.10, 7.59	0.29, 4.74	-96.64, -13.83
	Min, Max	0.2, 21.3	-70.6, 172.6	1.7, 21.4	-46.5, 75.0	0.0, 12.7	-99.6, 4.8
	Mean (SD)	7.85 (4.406)	-1.39 (50.850)	8.55 (5.219)	-4.48 (29.694)	3.08 (3.970)	-57.63 (39.814)
	95% CI of Mean	6.41, 9.28	-18.86, 16.08	6.72, 10.37	-15.58, 6.61	0.40, 5.75	-84.39, -30.88

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set****Parameter (units): NEQ (mg/g creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	43		29		9	
	Missing, n (%)	4 (8.5)		3 (9.4)		0	
	BLOQ, n(%)	5 (11.6)		4 (13.8)		0	
	Geometric Mean (CV%)	7.61 (66.661)		7.97 (46.895)		6.00 (48.827)	
	95% CI of Geometric Mean	6.31, 9.17		6.72, 9.44		4.20, 8.56	
	Median	8.25		7.97		6.19	
	Q25, Q75	6.27, 9.84		5.78, 11.21		5.81, 7.34	
	Min, Max	0.5, 33.6		3.1, 21.7		2.8, 12.8	
	Mean (SD)	8.73 (4.809)		8.79 (4.177)		6.57 (2.949)	
	95% CI of Mean	7.24, 10.21		7.19, 10.38		4.30, 8.84	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set****Parameter (units): NEQ (mg/g creat)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	43	32	29	9	9
	Missing, n (%)	0	4 (8.5)	0	3 (9.4)	0	
	BLOQ, n(%)	9 (19.1)		5 (15.6)		4 (44.4)	
	Geometric Mean (CV%)	6.52 (85.618)		7.40 (75.296)		0.82 (470.995)	
	95% CI of Geometric Mean	5.24, 8.11		5.81, 9.43		0.20, 3.21	
	Median	7.84	-7.82	7.88	-3.42	1.29	-65.37
	Q25, Q75	4.38, 10.74	-40.29, 20.95	5.01, 11.88	-22.41, 9.96	0.34, 2.34	-96.01, -31.70
	Min, Max	0.2, 13.8	-60.3, 103.4	1.2, 20.2	-61.1, 76.7	0.0, 5.8	-99.7, -15.2
	Mean (SD)	7.80 (3.688)	-3.86 (39.827)	8.94 (5.186)	-4.24 (32.726)	1.93 (1.941)	-63.38 (33.515)
	95% CI of Mean	6.71, 8.88	-16.12, 8.40	7.06, 10.81	-16.69, 8.22	0.43, 3.42	-89.14, -37.61

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set**

Parameter (units): NEQ (mg)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	69	31	22
	Missing, n (%)	6 (8.0)	4 (11.4)	2 (8.3)
	BLOQ, n(%)	7 (10.1)	3 (9.7)	0
	Geometric Mean (CV%)	12.54 (56.042)	13.40 (44.549)	12.17 (46.864)
	95% CI of Geometric Mean	11.05, 14.22	11.46, 15.67	9.98, 14.83
	Median	12.94	13.53	11.68
	Q25, Q75	9.93, 17.41	10.19, 19.21	8.90, 16.45
	Min, Max	1.1, 37.9	3.6, 27.4	4.9, 31.1
	Mean (SD)	14.04 (6.411)	14.49 (5.431)	13.38 (6.221)
	95% CI of Mean	12.49, 15.58	12.49, 16.48	10.62, 16.15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set**

Parameter (units): NEQ (mg)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 1	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	10 (13.5)	3 (8.6)	5 (21.7)
	Geometric Mean (CV%)	10.70 (54.276)	12.97 (56.207)	7.59 (58.540)
	95% CI of Geometric Mean	9.50, 12.04	10.83, 15.53	6.00, 9.61
	Median	11.13	13.40	7.28
	Q25, Q75	8.10, 15.38	10.19, 18.85	5.48, 11.22
	Min, Max	1.2, 30.7	2.6, 28.0	1.9, 17.9
	Mean (SD)	11.92 (5.253)	14.50 (6.257)	8.63 (4.225)
	95% CI of Mean	10.70, 13.14	12.34, 16.65	6.79, 10.46

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set**

Parameter (units): NEQ (mg)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 2	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	9 (12.2)	3 (8.6)	15 (65.2)
	Geometric Mean (CV%)	9.33 (59.167)	12.57 (60.110)	3.31 (50.162)
	95% CI of Geometric Mean	8.21, 10.60	10.39, 15.22	2.69, 4.07
	Median	9.92	12.52	3.10
	Q25, Q75	7.18, 13.66	9.90, 17.71	2.20, 4.25
	Min, Max	1.2, 26.1	1.7, 28.5	1.4, 8.0
	Mean (SD)	10.59 (4.993)	14.12 (5.943)	3.69 (1.778)
	95% CI of Mean	9.43, 11.75	12.08, 16.17	2.91, 4.46

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set**

Parameter (units): NEQ (mg)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 3	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	8 (10.8)	3 (8.6)	23 (100.0)
	Geometric Mean (CV%)	9.90 (61.914)	12.78 (57.283)	1.34 (66.102)
	95% CI of Geometric Mean	8.67, 11.30	10.64, 15.35	1.03, 1.74
	Median	10.61	13.04	1.56
	Q25, Q75	8.19, 14.87	9.97, 18.48	0.72, 2.08
	Min, Max	1.4, 28.9	1.5, 26.5	0.4, 4.0
	Mean (SD)	11.30 (5.292)	14.20 (5.663)	1.57 (0.874)
	95% CI of Mean	10.07, 12.53	12.25, 16.16	1.19, 1.96

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set**

Parameter (units): NEQ (mg)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 4	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	9 (12.2)	3 (8.6)	23 (100.0)
	Geometric Mean (CV%)	10.86 (64.347)	12.77 (58.640)	0.64 (75.040)
	95% CI of Geometric Mean	9.47, 12.45	10.59, 15.40	0.47, 0.86
	Median	11.42	13.45	0.66
	Q25, Q75	8.91, 15.86	10.89, 18.41	0.34, 1.08
	Min, Max	1.0, 28.4	1.9, 27.3	0.2, 2.5
	Mean (SD)	12.40 (5.685)	14.33 (6.121)	0.79 (0.569)
	95% CI of Mean	11.08, 13.72	12.23, 16.44	0.54, 1.04

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set**

Parameter (units): NEQ (mg)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Day 5	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	BLOQ, n(%)	11 (14.9)	4 (11.4)	22 (95.7)
	Geometric Mean (CV%)	11.67 (71.921)	14.17 (49.660)	0.37 (182.811)
	95% CI of Geometric Mean	10.04, 13.56	12.05, 16.65	0.21, 0.63
	Median	12.87	14.11	0.31
	Q25, Q75	9.41, 17.33	11.84, 20.66	0.17, 0.54
	Min, Max	0.5, 34.3	2.6, 28.8	0.1, 33.4
	Mean (SD)	13.59 (6.630)	15.47 (5.863)	1.82 (6.882)
	95% CI of Mean	12.05, 15.13	13.45, 17.49	-1.16, 4.80

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set**

Parameter (units): NEQ (mg)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	37	30	12
	Missing, n (%)	3 (7.5)	4 (11.8)	1 (7.7)
	BLOQ, n(%)	4 (10.8)	4 (13.3)	0
	Geometric Mean (CV%)	12.60 (63.418)	13.41 (45.563)	12.39 (51.431)
	95% CI of Geometric Mean	10.38, 15.31	11.40, 15.78	9.10, 16.86
	Median	12.41	13.73	10.75
	Q25, Q75	9.41, 17.41	10.19, 19.21	8.64, 18.02
	Min, Max	1.1, 37.9	3.6, 27.4	6.0, 31.1
	Mean (SD)	14.39 (7.149)	14.54 (5.527)	13.87 (7.373)
	95% CI of Mean	12.00, 16.78	12.48, 16.61	9.18, 18.56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set**

Parameter (units): NEQ (mg)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Day 30	n	40	34	13
	BLOQ, n(%)	5 (12.5)	5 (14.7)	4 (30.8)
	Geometric Mean (CV%)	12.38 (74.402)	13.06 (63.298)	2.16 (485.327)
	95% CI of Geometric Mean	10.01, 15.31	10.66, 16.00	0.73, 6.38
	Median	14.33	14.00	5.38
	Q25, Q75	9.26, 19.86	10.92, 21.07	0.90, 7.26
	Min, Max	0.8, 31.6	2.2, 27.2	0.1, 14.5
	Mean (SD)	14.54 (7.251)	14.92 (6.819)	5.29 (5.053)
	95% CI of Mean	12.22, 16.87	12.54, 17.31	2.23, 8.35

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set**

Parameter (units): NEQ (mg)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	36	31	12
	Missing, n (%)	3 (7.7)	4 (11.4)	0
	BLOQ, n(%)	5 (13.9)	4 (12.9)	0
	Geometric Mean (CV%)	12.32 (70.822)	13.27 (45.213)	10.27 (47.311)
	95% CI of Geometric Mean	9.92, 15.29	11.32, 15.55	7.71, 13.67
	Median	13.39	13.53	9.49
	Q25, Q75	9.20, 17.83	9.61, 19.21	8.35, 14.01
	Min, Max	1.1, 37.9	3.6, 27.4	4.9, 22.5
	Mean (SD)	14.41 (7.490)	14.38 (5.507)	11.30 (5.407)
	95% CI of Mean	11.87, 16.94	12.36, 16.41	7.86, 14.74

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set**

Parameter (units): NEQ (mg)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Day 60	n	39	35	12
	BLOQ, n(%)	6 (15.4)	4 (11.4)	6 (50.0)
	Geometric Mean (CV%)	10.34 (83.753)	11.87 (76.037)	1.55 (574.894)
	95% CI of Geometric Mean	8.16, 13.10	9.41, 14.98	0.46, 5.11
	Median	10.78	12.97	2.11
	Q25, Q75	7.78, 17.80	8.96, 20.56	0.37, 7.15
	Min, Max	0.5, 25.9	1.8, 29.8	0.1, 22.9
	Mean (SD)	12.44 (6.474)	14.19 (7.536)	4.90 (6.719)
	95% CI of Mean	10.34, 14.54	11.59, 16.78	0.63, 9.17

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set**

Parameter (units): NEQ (mg)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	44	29	9
	Missing, n (%)	3 (6.4)	3 (9.4)	0
	BLOQ, n(%)	5 (11.4)	4 (13.8)	0
	Geometric Mean (CV%)	12.41 (65.389)	13.04 (45.472)	9.73 (45.836)
	95% CI of Geometric Mean	10.34, 14.88	11.05, 15.38	6.95, 13.62
	Median	12.78	13.53	9.62
	Q25, Q75	9.56, 17.68	9.61, 17.87	8.38, 11.52
	Min, Max	1.1, 37.9	3.6, 27.4	4.9, 19.5
	Mean (SD)	14.30 (7.220)	14.14 (5.443)	10.59 (4.721)
	95% CI of Mean	12.10, 16.50	12.06, 16.22	6.96, 14.23

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.1 Descriptive Statistics of NEQ in 24-hour Urine Collection - PP Set**

Parameter (units): NEQ (mg)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Day 90	n	47	32	9
	BLOQ, n(%)	9 (19.1)	5 (15.6)	4 (44.4)
	Geometric Mean (CV%)	10.93 (75.689)	12.29 (75.748)	1.40 (526.664)
	95% CI of Geometric Mean	8.97, 13.33	9.63, 15.67	0.34, 5.74
	Median	12.68	14.36	3.06
	Q25, Q75	7.23, 16.24	9.41, 19.17	0.36, 4.77
	Min, Max	0.6, 29.5	1.5, 29.6	0.0, 9.1
	Mean (SD)	12.87 (6.371)	14.60 (7.453)	3.47 (3.394)
	95% CI of Mean	10.99, 14.74	11.91, 17.29	0.85, 6.08

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg/g creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	71		36		36	
	Missing, n (%)	9 (11.3)		5 (12.2)		3 (7.7)	
	BLOQ, n(%)	7 (9.9)		4 (11.1)		0	
	Geometric Mean (CV%)	7.47 (56.999)		8.36 (43.989)		7.96 (51.195)	
	95% CI of Geometric Mean	6.58, 8.48		7.25, 9.64		6.76, 9.38	
	Median	7.80		8.54		8.47	
	Q25, Q75	6.27, 9.94		6.28, 11.17		5.81, 10.25	
	Min, Max	0.5, 33.6		3.1, 21.7		2.8, 28.8	
	Mean (SD)	8.36 (4.139)		9.11 (3.922)		8.91 (4.645)	
	95% CI of Mean	7.37, 9.34		7.77, 10.44		7.34, 10.49	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg/g creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	10 (13.0)		4 (10.0)		6 (16.2)	
	Geometric Mean (CV%)	6.40 (56.682)		7.95 (53.104)		5.34 (57.303)	
	95% CI of Geometric Mean	5.67, 7.22		6.77, 9.33		4.47, 6.38	
	Median	6.86	-15.03	8.09	-2.75	5.19	-36.09
	Q25, Q75	5.47, 8.77	-23.07, -2.84	5.75, 11.99	-11.40, 9.42	3.80, 8.00	-38.60, -24.10
	Min, Max	0.5, 19.2	-43.9, 63.4	2.0, 20.9	-39.5, 30.7	1.9, 17.3	-75.8, 0.0
	Mean (SD)	7.14 (3.016)	-12.24 (18.774)	8.87 (4.046)	-1.86 (14.870)	6.13 (3.404)	-31.24 (16.993)
	95% CI of Mean	6.45, 7.83	-16.69, -7.80	7.57, 10.17	-6.90, 3.18	4.99, 7.27	-36.99, -25.48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg/g creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	9 (11.7)		4 (10.0)		22 (59.5)	
	Geometric Mean (CV%)	5.58 (60.767)		7.79 (57.831)		2.57 (80.455)	
	95% CI of Geometric Mean	4.91, 6.34		6.56, 9.26		2.03, 3.26	
	Median	6.04	-20.63	7.94	-0.14	2.10	-72.87
	Q25, Q75	4.64, 8.17	-37.70, -6.46	5.53, 12.29	-12.29, 8.33	1.71, 3.80	-76.60, -66.20
	Min, Max	0.6, 15.4	-71.5, 44.5	1.6, 20.5	-52.5, 27.2	0.7, 13.1	-82.3, 0.0
	Mean (SD)	6.32 (2.852)	-20.81 (24.780)	8.81 (4.132)	-3.17 (17.536)	3.39 (3.091)	-62.49 (26.463)
	95% CI of Mean	5.67, 6.98	-26.69, -14.94	7.49, 10.14	-9.11, 2.76	2.36, 4.43	-71.45, -53.53

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg/g creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	8 (10.4)		4 (10.0)		32 (86.5)	
	Geometric Mean (CV%)	5.89 (62.978)		8.04 (54.805)		1.22 (126.339)	
	95% CI of Geometric Mean	5.16, 6.72		6.82, 9.48		0.87, 1.69	
	Median	6.11	-18.31	8.29	1.58	0.93	-87.95
	Q25, Q75	4.95, 8.26	-36.44, 1.27	6.30, 11.81	-16.67, 17.92	0.76, 1.96	-90.98, -82.46
	Min, Max	0.5, 19.0	-66.1, 52.2	1.5, 19.3	-50.9, 36.2	0.3, 13.1	-95.1, 0.0
	Mean (SD)	6.70 (3.078)	-14.89 (28.787)	8.99 (3.966)	0.39 (20.239)	2.23 (3.359)	-75.86 (31.165)
	95% CI of Mean	5.99, 7.40	-21.70, -8.07	7.71, 10.26	-6.47, 7.24	1.10, 3.35	-86.40, -65.31

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg/g creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	9 (11.7)		4 (10.0)		32 (86.5)	
	Geometric Mean (CV%)	6.45 (67.348)		8.34 (56.093)		0.61 (192.090)	
	95% CI of Geometric Mean	5.61, 7.41		7.05, 9.86		0.40, 0.93	
	Median	7.20	-10.64	8.56	7.79	0.45	-93.94
	Q25, Q75	5.05, 8.97	-28.03, 9.73	6.58, 13.27	-6.10, 17.84	0.30, 0.98	-96.51, -91.49
	Min, Max	0.3, 18.2	-58.4, 75.3	1.7, 19.5	-54.0, 54.6	0.1, 13.1	-98.6, 0.0
	Mean (SD)	7.37 (3.339)	-6.74 (29.945)	9.36 (4.133)	5.09 (23.627)	1.76 (3.507)	-81.29 (33.198)
	95% CI of Mean	6.61, 8.13	-13.84, 0.35	8.03, 10.68	-2.91, 13.09	0.58, 2.93	-92.52, -70.05

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg/g creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	12 (15.6)		5 (12.5)		31 (83.8)	
	Geometric Mean (CV%)	6.75 (73.294)		8.73 (50.204)		0.35 (361.598)	
	95% CI of Geometric Mean	5.81, 7.84		7.49, 10.16		0.20, 0.60	
	Median	7.23	-5.74	8.47	6.96	0.21	-97.42
	Q25, Q75	5.67, 9.41	-22.76, 17.25	6.73, 12.77	-0.04, 21.23	0.13, 0.54	-98.48, -94.45
	Min, Max	0.2, 20.5	-66.0, 108.1	2.1, 21.7	-32.0, 35.7	0.0, 13.1	-99.0, 0.0
	Mean (SD)	7.79 (3.611)	-1.35 (33.568)	9.65 (4.203)	7.32 (16.771)	1.88 (4.009)	-81.21 (36.547)
	95% CI of Mean	6.97, 8.61	-9.30, 6.61	8.30, 11.00	1.64, 13.00	0.54, 3.22	-93.58, -68.84

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg/g creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	10 (13.0)		5 (12.5)		12 (32.4)	
	Geometric Mean (CV%)	7.67 (67.466)		8.18 (66.279)		2.97 (231.517)	
	95% CI of Geometric Mean	6.67, 8.82		6.74, 9.92		1.88, 4.68	
	Median	7.89	2.00	8.48	9.96	4.15	-42.42
	Q25, Q75	6.33, 10.64	-17.04, 25.69	5.49, 14.18	-17.77, 22.42	2.21, 6.74	-78.89, -8.80
	Min, Max	0.3, 22.1	-62.7, 152.2	1.9, 20.7	-52.3, 58.4	0.1, 14.6	-99.5, 26.0
	Mean (SD)	8.82 (4.258)	9.00 (42.142)	9.56 (4.951)	4.95 (27.845)	5.07 (3.945)	-43.18 (37.092)
	95% CI of Mean	7.85, 9.79	-0.98, 18.98	7.97, 11.15	-4.48, 14.38	3.75, 6.39	-55.74, -30.63

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg/g creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	9 (11.7)		4 (10.0)		9 (24.3)	
	Geometric Mean (CV%)	7.05 (74.062)		7.74 (71.925)		3.41 (220.986)	
	95% CI of Geometric Mean	6.06, 8.20		6.29, 9.52		2.19, 5.33	
	Median	7.82	2.18	8.13	-2.51	4.69	-42.18
	Q25, Q75	5.04, 10.65	-29.39, 27.02	5.45, 12.90	-21.14, 24.60	3.58, 6.62	-64.15, -1.95
	Min, Max	0.2, 21.3	-70.6, 177.8	1.7, 21.4	-46.5, 75.0	0.0, 14.1	-99.6, 18.1
	Mean (SD)	8.27 (4.226)	5.82 (51.166)	9.26 (5.176)	0.64 (30.080)	5.38 (3.798)	-37.88 (34.936)
	95% CI of Mean	7.30, 9.23	-6.29, 17.94	7.60, 10.92	-9.54, 10.82	4.11, 6.66	-49.71, -26.06

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg/g creat)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	77	71	40	36	37	36
	Missing, n (%)	3 (3.8)	9 (11.3)	1 (2.4)	5 (12.2)	2 (5.1)	3 (7.7)
	BLOQ, n(%)	12 (15.6)		5 (12.5)		6 (16.2)	
	Geometric Mean (CV%)	6.91 (72.494)		7.79 (75.798)		3.91 (222.398)	
	95% CI of Geometric Mean	5.96, 8.02		6.28, 9.67		2.50, 6.10	
	Median	7.89	2.16	8.39	1.49	5.10	-25.51
	Q25, Q75	5.54, 10.38	-25.48, 20.95	5.45, 14.05	-20.25, 19.97	2.38, 9.01	-61.37, -4.19
	Min, Max	0.2, 22.1	-79.0, 185.2	1.2, 20.2	-61.1, 76.7	0.0, 24.5	-99.7, 6.9
	Mean (SD)	8.04 (3.850)	2.02 (43.737)	9.38 (5.128)	0.41 (32.196)	6.29 (4.977)	-32.34 (31.994)
	95% CI of Mean	7.16, 8.92	-8.33, 12.38	7.73, 11.02	-10.49, 11.31	4.63, 7.95	-43.17, -21.51

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	73	37	37
	Missing, n (%)	7 (8.8)	4 (9.8)	2 (5.1)
	BLOQ, n(%)	7 (9.6)	4 (10.8)	0
	Geometric Mean (CV%)	12.47 (54.594)	13.56 (42.257)	12.92 (47.655)
	95% CI of Geometric Mean	11.06, 14.05	11.84, 15.53	11.10, 15.03
	Median	12.94	13.53	13.24
	Q25, Q75	9.93, 17.37	10.82, 17.92	9.10, 19.53
	Min, Max	1.1, 37.9	3.6, 27.4	4.9, 31.1
	Mean (SD)	13.90 (6.280)	14.57 (5.213)	14.25 (6.462)
	95% CI of Mean	12.43, 15.37	12.82, 16.31	12.09, 16.41

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 1	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	10 (12.8)	4 (9.8)	6 (15.8)
	Geometric Mean (CV%)	10.65 (53.178)	13.00 (52.665)	8.80 (58.862)
	95% CI of Geometric Mean	9.52, 11.93	11.12, 15.20	7.35, 10.53
	Median	11.13	13.36	8.69
	Q25, Q75	8.10, 15.18	10.32, 18.79	6.12, 12.78
	Min, Max	1.2, 30.7	2.6, 28.0	1.9, 29.2
	Mean (SD)	11.84 (5.164)	14.38 (5.974)	10.10 (5.499)
	95% CI of Mean	10.67, 13.01	12.49, 16.28	8.29, 11.91

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 2	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	9 (11.5)	4 (9.8)	23 (60.5)
	Geometric Mean (CV%)	9.30 (57.556)	12.89 (56.224)	4.10 (80.450)
	95% CI of Geometric Mean	8.24, 10.50	10.92, 15.21	3.25, 5.18
	Median	9.86	13.09	3.72
	Q25, Q75	7.19, 13.66	10.95, 17.71	2.52, 6.63
	Min, Max	1.2, 26.1	1.7, 28.5	1.4, 29.2
	Mean (SD)	10.50 (4.888)	14.30 (5.685)	5.54 (5.770)
	95% CI of Mean	9.40, 11.61	12.50, 16.10	3.64, 7.44

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 3	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	8 (10.3)	4 (9.8)	33 (86.8)
	Geometric Mean (CV%)	9.82 (60.232)	13.17 (53.785)	1.87 (133.492)
	95% CI of Geometric Mean	8.65, 11.13	11.23, 15.45	1.34, 2.61
	Median	10.31	13.78	1.68
	Q25, Q75	8.06, 14.78	10.72, 18.18	1.00, 2.39
	Min, Max	1.4, 28.9	1.5, 26.5	0.4, 29.2
	Mean (SD)	11.15 (5.197)	14.49 (5.516)	3.67 (6.219)
	95% CI of Mean	9.97, 12.33	12.74, 16.24	1.63, 5.72

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 4	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	9 (11.5)	4 (9.8)	33 (86.8)
	Geometric Mean (CV%)	10.80 (62.972)	13.49 (56.207)	0.94 (206.215)
	95% CI of Geometric Mean	9.48, 12.31	11.43, 15.92	0.61, 1.45
	Median	11.27	15.60	0.72
	Q25, Q75	8.78, 15.59	11.24, 18.41	0.41, 1.25
	Min, Max	1.0, 28.4	1.9, 27.5	0.2, 29.2
	Mean (SD)	12.29 (5.604)	15.00 (6.083)	2.97 (6.430)
	95% CI of Mean	11.02, 13.56	13.08, 16.93	0.85, 5.09

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 5	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	12 (15.4)	5 (12.2)	32 (84.2)
	Geometric Mean (CV%)	11.67 (69.968)	14.51 (47.219)	0.57 (381.558)
	95% CI of Geometric Mean	10.11, 13.46	12.59, 16.72	0.32, 0.98
	Median	12.87	14.11	0.32
	Q25, Q75	9.41, 17.33	12.19, 20.66	0.19, 0.79
	Min, Max	0.5, 34.3	2.6, 28.8	0.1, 33.4
	Mean (SD)	13.50 (6.499)	15.74 (5.736)	3.50 (8.205)
	95% CI of Mean	12.03, 14.97	13.92, 17.55	0.80, 6.20

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	10 (12.8)	5 (12.2)	13 (34.2)
	Geometric Mean (CV%)	12.56 (61.908)	13.16 (63.537)	4.61 (243.976)
	95% CI of Geometric Mean	11.04, 14.29	10.94, 15.82	2.91, 7.28
	Median	13.91	14.18	6.93
	Q25, Q75	9.36, 18.97	11.00, 21.00	2.51, 10.73
	Min, Max	0.8, 31.6	2.2, 28.0	0.1, 29.2
	Mean (SD)	14.30 (6.592)	15.04 (6.812)	8.13 (6.804)
	95% CI of Mean	12.80, 15.79	12.88, 17.19	5.88, 10.37

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	9 (11.5)	4 (9.8)	10 (26.3)
	Geometric Mean (CV%)	11.44 (69.099)	12.65 (72.089)	5.42 (248.551)
	95% CI of Geometric Mean	9.93, 13.18	10.31, 15.52	3.41, 8.61
	Median	12.03	13.09	7.72
	Q25, Q75	8.60, 18.13	9.51, 20.56	5.01, 10.74
	Min, Max	0.5, 27.5	1.8, 29.8	0.1, 29.2
	Mean (SD)	13.27 (6.372)	14.84 (7.276)	9.09 (6.896)
	95% CI of Mean	11.82, 14.71	12.54, 17.15	6.82, 11.37

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.18.2 Descriptive Statistics of NEQ in 24-hour Urine Collection - FAS****Parameter (units): NEQ (mg)**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	BLOQ, n(%)	12 (15.4)	5 (12.2)	7 (18.4)
	Geometric Mean (CV%)	11.68 (66.564)	12.38 (71.800)	5.97 (237.655)
	95% CI of Geometric Mean	10.18, 13.39	10.09, 15.18	3.79, 9.39
	Median	13.27	14.95	8.34
	Q25, Q75	8.10, 16.78	9.80, 18.22	4.77, 14.25
	Min, Max	0.6, 29.5	1.5, 29.6	0.0, 30.3
	Mean (SD)	13.44 (6.331)	14.49 (6.993)	9.92 (7.821)
	95% CI of Mean	12.01, 14.87	12.28, 16.71	7.35, 12.50

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Baseline, 08:00 PM - 09:30 PM	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	16.8385 (55.67901)	17.3220 (50.63008)	17.3857 (54.47735)
	95% CI of Geometric Mean	14.9284, 18.9928	14.7004, 20.4111	13.9460, 21.6736
	Median	17.5000	18.0000	20.9000
	Q25, Q75	13.2000, 22.9000	14.8000, 25.1000	13.4000, 24.8000
	Min, Max	1.580, 47.300	4.960, 43.700	5.220, 32.000

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 1, 08:00 PM - 09:30 PM	n	74	34	23
	Missing, n (%)	1 (1.3)	1 (2.9)	1 (4.2)
	BLOQ, n(%)	3 (4.1)	0	4 (17.4)
	Geometric Mean (CV%)	8.7752 (106.51577)	15.2833 (64.02247)	0.3925 (126.48241)
	95% CI of Geometric Mean	7.1720, 10.7368	12.4567, 18.7513	0.2572, 0.5990
	Median	10.9500	17.3000	0.3460
	Q25, Q75	6.6600, 15.8000	12.8000, 20.2000	0.2200, 0.7460
	Min, Max	0.500, 29.200	2.010, 42.700	0.100, 6.250

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 2, 08:00 PM - 09:30 PM	n	74	34	23
	Missing, n (%)	1 (1.3)	1 (2.9)	1 (4.2)
	BLOQ, n(%)	0	0	12 (52.2)
	Geometric Mean (CV%)	11.8831 (73.19577)	15.7868 (65.34164)	0.1746 (69.57267)
	95% CI of Geometric Mean	10.2099, 13.8304	12.8215, 19.4380	0.1330, 0.2292
	Median	13.3000	16.5500	0.1000
	Q25, Q75	8.6400, 18.7000	13.1000, 24.5000	0.1000, 0.3170
	Min, Max	1.100, 36.100	2.850, 40.300	0.100, 0.604

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 3, 08:00 PM - 09:30 PM	n	74	33	23
	Missing, n (%)	1 (1.3)	2 (5.7)	1 (4.2)
	BLOQ, n(%)	1 (1.4)	0	16 (69.6)
	Geometric Mean (CV%)	12.7874 (77.19410)	17.1134 (58.92303)	0.1351 (51.38907)
	95% CI of Geometric Mean	10.9141, 14.9822	14.1016, 20.7685	0.1095, 0.1666
	Median	13.6000	17.3000	0.1000
	Q25, Q75	9.2700, 21.1000	14.1000, 23.7000	0.1000, 0.2060
	Min, Max	0.500, 33.400	3.260, 39.700	0.100, 0.399

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 4, 08:00 PM - 09:30 PM	n	74	34	23
	Missing, n (%)	1 (1.3)	1 (2.9)	1 (4.2)
	BLOQ, n(%)	1 (1.4)	0	20 (87.0)
	Geometric Mean (CV%)	11.8577 (76.52119)	14.8317 (59.16170)	0.1116 (30.01240)
	95% CI of Geometric Mean	10.1318, 13.8775	12.2511, 17.9558	0.0982, 0.1268
	Median	13.5500	14.2000	0.1000
	Q25, Q75	9.5600, 18.0000	12.0000, 21.5000	0.1000, 0.1000
	Min, Max	0.500, 30.700	3.250, 37.500	0.100, 0.278

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 5, 15 min < T0	n	66	31	0
	Missing, n (%)	9 (12.0)	4 (11.4)	
	BLOQ, n(%)	18 (27.3)	4 (12.9)	
	Geometric Mean (CV%)	1.5497 (97.48890)	2.0940 (77.97180)	
	95% CI of Geometric Mean	1.2676, 1.8946	1.6262, 2.6964	
	Median	1.8450	2.2700	
	Q25, Q75	0.5000, 3.0200	1.6100, 3.4100	
	Min, Max	0.500, 5.800	0.500, 5.350	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 5, T0 + 2 h	n	31	15	0
	Missing, n (%)	44 (58.7)	20 (57.1)	
	BLOQ, n(%)	2 (6.5)	0	
	Geometric Mean (CV%)	8.4013 (115.45495)	11.8121 (57.70739)	
	95% CI of Geometric Mean	5.9941, 11.7752	8.7777, 15.8954	
	Median	9.6700	11.9000	
	Q25, Q75	6.5200, 16.2000	8.0100, 17.7000	
	Min, Max	0.500, 21.800	5.080, 31.200	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 5, T0 + 4 h	n	29	14	0
	Missing, n (%)	46 (61.3)	21 (60.0)	
	BLOQ, n(%)	1 (3.4)	0	
	Geometric Mean (CV%)	10.7427 (101.75302)	12.2578 (70.51522)	
	95% CI of Geometric Mean	7.7956, 14.8040	8.4938, 17.6897	
	Median	12.4000	10.1200	
	Q25, Q75	9.7900, 15.6000	9.1800, 19.8000	
	Min, Max	0.500, 27.100	3.060, 28.700	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 5, T0 + 6 h	n	37	14	0
	Missing, n (%)	38 (50.7)	21 (60.0)	
	BLOQ, n(%)	1 (2.7)	0	
	Geometric Mean (CV%)	11.6285 (87.72947)	14.5256 (71.73575)	
	95% CI of Geometric Mean	9.0391, 14.9597	10.0130, 21.0719	
	Median	13.2000	17.3000	
	Q25, Q75	9.4000, 18.0000	10.5000, 22.6000	
	Min, Max	0.500, 36.200	3.170, 28.200	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 5, T0 + 8 h	n	35	11	0
	Missing, n (%)	40 (53.3)	24 (68.6)	
	BLOQ, n(%)	2 (5.7)	0	
	Geometric Mean (CV%)	11.9998 (117.73155)	13.8818 (59.27604)	
	95% CI of Geometric Mean	8.7106, 16.5310	9.6016, 20.0701	
	Median	14.8000	14.5000	
	Q25, Q75	8.5600, 20.7000	11.2000, 20.5000	
	Min, Max	0.500, 29.400	3.470, 30.000	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 5, T0 + 10 h	n	36	13	0
	Missing, n (%)	39 (52.0)	22 (62.9)	
	BLOQ, n(%)	1 (2.8)	0	
	Geometric Mean (CV%)	14.2725 (89.58512)	14.8703 (70.48027)	
	95% CI of Geometric Mean	11.0079, 18.5052	10.1310, 21.8266	
	Median	16.9000	16.4000	
	Q25, Q75	11.3000, 23.9500	9.1000, 22.3000	
	Min, Max	0.500, 32.600	5.010, 37.700	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 5, T0 + 12 h	n	33	14	0
	Missing, n (%)	42 (56.0)	21 (60.0)	
	BLOQ, n(%)	2 (6.1)	0	
	Geometric Mean (CV%)	12.9048 (134.97255)	14.1189 (67.50937)	
	95% CI of Geometric Mean	8.9930, 18.5181	9.9114, 20.1124	
	Median	18.4000	16.3000	
	Q25, Q75	10.5000, 23.4000	10.0000, 21.3000	
	Min, Max	0.500, 33.300	3.240, 32.500	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 5, T0 + 14 h	n	30	19	0
	Missing, n (%)	45 (60.0)	16 (45.7)	
	BLOQ, n(%)	1 (3.3)	0	
	Geometric Mean (CV%)	14.2264 (125.42616)	16.7668 (52.57178)	
	95% CI of Geometric Mean	9.8955, 20.4528	13.2143, 21.2743	
	Median	20.5000	18.0000	
	Q25, Q75	14.1000, 24.9000	11.2000, 24.4000	
	Min, Max	0.500, 36.500	6.650, 34.100	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 5, T0 + 16 h	n	32	15	0
	Missing, n (%)	43 (57.3)	20 (57.1)	
	BLOQ, n(%)	2 (6.3)	0	
	Geometric Mean (CV%)	18.2542 (136.68239)	20.1499 (44.57363)	
	95% CI of Geometric Mean	12.6076, 26.4297	15.9180, 25.5069	
	Median	23.8500	18.8000	
	Q25, Q75	17.3000, 30.2000	14.9000, 26.7000	
	Min, Max	0.500, 44.400	7.670, 38.400	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 5, 08:00 PM - 09:30 PM	n	0	0	23
	Missing, n (%)			1 (4.2)
	BLOQ, n(%)			23 (100.0)
	Geometric Mean (CV%)			0.1000 (0.00000)
	95% CI of Geometric Mean			NA, NA
	Median			0.1000
	Q25, Q75			0.1000, 0.1000
	Min, Max			0.100, 0.100

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 6/Discharge Confinement, n 08:00 AM - 09:30 AM		0	0	23
	Missing, n (%)			1 (4.2)
	BLOQ, n(%)			22 (95.7)
	Geometric Mean (CV%)			0.1060 (28.32654)
	95% CI of Geometric Mean			0.0939, 0.1195
	Median			0.1000
	Q25, Q75			0.1000, 0.1000
	Min, Max			0.100, 0.379

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 6/Discharge Confinement, n		27	14	0
T0 + 20 h				
	Missing, n (%)	48 (64.0)	21 (60.0)	
	BLOQ, n(%)	2 (7.4)	0	
	Geometric Mean (CV%)	5.8819 (110.95920)	6.4711 (48.35424)	
	95% CI of Geometric Mean	4.1268, 8.3836	4.9663, 8.4318	
	Median	6.5700	7.1800	
	Q25, Q75	3.8500, 12.1000	4.6400, 9.0900	
	Min, Max	0.500, 18.500	3.220, 14.300	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Nicotine (ng/mL)				
Day 6/Discharge Confinement, n		27	8	0
T0 + 24 h				
	Missing, n (%)	48 (64.0)	27 (77.1)	
	BLOQ, n(%)	8 (29.6)	2 (25.0)	
	Geometric Mean (CV%)	1.6586 (116.79348)	2.0080 (113.48497)	
	95% CI of Geometric Mean	1.1491, 2.3939	0.9385, 4.2960	
	Median	2.1400	2.9900	
	Q25, Q75	0.5000, 3.5200	1.1800, 3.8700	
	Min, Max	0.500, 6.640	0.500, 4.530	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
Nicotine (ng/mL)				
Baseline, 08:00 PM - 09:30 PM	n	40	34	13
	Geometric Mean (CV%)	15.7473 (65.62443)	17.3498 (51.42877)	18.4448 (39.72246)
	95% CI of Geometric Mean	13.0042, 19.0689	14.6516, 20.5448	14.6359, 23.2450
	Median	16.2500	17.5500	19.6000
	Q25, Q75	12.9500, 22.3500	14.8000, 25.1000	16.3000, 23.9000
	Min, Max	1.580, 47.300	4.960, 43.700	7.440, 28.300

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
Nicotine (ng/mL)				
Day 30, 10:00 AM - 11:30 AM	n	39	33	13
	Missing, n (%)	1 (2.5)	1 (2.9)	0
	BLOQ, n(%)	0	0	4 (30.8)
	Geometric Mean (CV%)	11.2602 (84.75809)	13.0615 (49.98100)	0.5725 (268.12758)
	95% CI of Geometric Mean	8.8707, 14.2934	11.0477, 15.4423	0.2383, 1.3751
	Median	13.2000	14.2000	0.7120
	Q25, Q75	8.2800, 17.6000	10.5000, 16.2000	0.1000, 1.5300
	Min, Max	1.030, 33.000	3.170, 28.600	0.100, 4.670

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
Nicotine (ng/mL)				
Baseline, 08:00 PM - 09:30 PM	n	39	35	12
	Geometric Mean (CV%)	15.6685 (70.36541)	17.3680 (50.58091)	14.4642 (54.21497)
	95% CI of Geometric Mean	12.7568, 19.2448	14.7416, 20.4624	10.4766, 19.9695
	Median	16.5000	18.0000	17.0000
	Q25, Q75	12.7000, 22.9000	14.8000, 25.1000	10.5150, 21.2500
	Min, Max	1.580, 47.300	4.960, 43.700	5.220, 27.500

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
Nicotine (ng/mL)				
Day 60, 10:00 AM - 11:30 AM	n	39	33	11
	Missing, n (%)	0	2 (5.7)	1 (8.3)
	BLOQ, n(%)	1 (2.6)	0	5 (45.5)
	Geometric Mean (CV%)	10.9846 (82.32736)	13.8396 (53.58589)	0.7642 (838.79771)
	95% CI of Geometric Mean	8.6998, 13.8694	11.5812, 16.5384	0.1907, 3.0617
	Median	12.0000	14.1000	1.5400
	Q25, Q75	9.0900, 17.1000	11.7000, 19.6000	0.1000, 3.9200
	Min, Max	0.500, 34.300	3.740, 33.900	0.100, 19.300

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
Nicotine (ng/mL)				
Baseline, 08:00 PM - 09:30 PM	n	47	32	9
	Geometric Mean (CV%)	15.9692 (66.42061)	17.2801 (47.35088)	14.0195 (57.56535)
	95% CI of Geometric Mean	13.3720, 19.0709	14.6933, 20.3224	9.2925, 21.1508
	Median	16.5000	17.4500	16.3000
	Q25, Q75	12.7000, 22.9000	14.9000, 23.2500	12.1000, 18.2000
	Min, Max	1.580, 47.300	4.960, 43.700	5.220, 27.500

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
Nicotine (ng/mL)				
Day 90, 10:00 AM - 12:30 PM	n	47	31	9
	Missing, n (%)	0	1 (3.1)	0
	BLOQ, n(%)	1 (2.1)	0	2 (22.2)
	Geometric Mean (CV%)	8.8222 (90.51843)	12.6521 (56.05491)	0.7381 (261.02552)
	95% CI of Geometric Mean	7.0295, 11.0720	10.4446, 15.3262	0.2451, 2.2221
	Median	10.5000	13.9000	1.1000
	Q25, Q75	6.6800, 14.0000	8.4400, 19.1000	0.2200, 2.1600
	Min, Max	0.500, 27.900	3.510, 28.000	0.100, 4.360

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Baseline, 08:00 PM - 09:30 PM	n	74	35	23
	Missing, n (%)	1 (1.3)	0	1 (4.2)
	Geometric Mean (CV%)	213.940 (52.1228)	228.302 (45.3425)	262.308 (51.0224)
	95% CI of Geometric Mean	190.969, 239.673	196.789, 264.862	213.047, 322.959
	Median	226.500	222.000	279.000
	Q25, Q75	153.000, 282.000	173.000, 302.000	199.000, 375.000
	Min, Max	21.00, 605.00	65.90, 450.00	96.80, 561.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 1, 08:00 PM - 09:30 PM	n	74	34	23
	Missing, n (%)	1 (1.3)	1 (2.9)	1 (4.2)
	Geometric Mean (CV%)	171.735 (58.7104)	221.785 (46.6616)	116.720 (60.3486)
	95% CI of Geometric Mean	151.391, 194.812	189.966, 258.934	91.724, 148.527
	Median	182.500	234.000	115.000
	Q25, Q75	130.000, 243.000	175.000, 276.000	78.000, 203.000
	Min, Max	20.50, 475.00	56.60, 456.00	43.10, 329.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 2, 08:00 PM - 09:30 PM	n	74	34	23
	Missing, n (%)	1 (1.3)	1 (2.9)	1 (4.2)
	Geometric Mean (CV%)	164.961 (63.5472)	217.107 (51.0524)	51.721 (80.6376)
	95% CI of Geometric Mean	144.138, 188.792	183.547, 256.804	38.084, 70.241
	Median	176.500	229.500	50.000
	Q25, Q75	122.000, 250.000	165.000, 293.000	28.900, 88.700
	Min, Max	23.90, 451.00	48.20, 455.00	16.70, 165.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 3, 08:00 PM - 09:30 PM	n	74	33	23
	Missing, n (%)	1 (1.3)	2 (5.7)	1 (4.2)
	Geometric Mean (CV%)	181.019 (63.5385)	228.485 (51.7709)	23.274 (100.3543)
	95% CI of Geometric Mean	158.172, 207.167	192.228, 271.581	16.222, 33.391
	Median	194.000	236.000	21.500
	Q25, Q75	149.000, 258.000	174.000, 306.000	11.300, 52.300
	Min, Max	15.90, 493.00	40.40, 466.00	7.02, 85.40

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 4, 08:00 PM - 09:30 PM	n	74	34	23
	Missing, n (%)	1 (1.3)	1 (2.9)	1 (4.2)
	Geometric Mean (CV%)	185.916 (64.7867)	230.513 (46.1827)	10.099 (121.4186)
	95% CI of Geometric Mean	162.087, 213.247	197.727, 268.735	6.691, 15.242
	Median	202.000	240.500	9.860
	Q25, Q75	147.000, 268.000	182.000, 298.000	3.850, 26.100
	Min, Max	8.54, 459.00	51.80, 456.00	2.62, 51.30

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 5, 15 min < T0	n	65	30	0
	Missing, n (%)	10 (13.3)	5 (14.3)	
	Geometric Mean (CV%)	161.927 (71.4950)	214.771 (49.2508)	
	95% CI of Geometric Mean	138.093, 189.875	180.468, 255.594	
	Median	174.000	227.500	
	Q25, Q75	128.000, 239.000	168.000, 283.000	
	Min, Max	6.88, 462.00	53.00, 452.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 5, T0 + 2 h	n	29	15	0
	Missing, n (%)	46 (61.3)	20 (57.1)	
	Geometric Mean (CV%)	185.460 (42.5936)	217.560 (52.5713)	
	95% CI of Geometric Mean	158.781, 216.622	165.490, 286.013	
	Median	195.000	241.000	
	Q25, Q75	137.000, 247.000	198.000, 266.000	
	Min, Max	63.90, 385.00	51.70, 437.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 5, T0 + 4 h	n	28	14	0
	Missing, n (%)	47 (62.7)	21 (60.0)	
	Geometric Mean (CV%)	200.877 (43.5921)	218.174 (55.5048)	
	95% CI of Geometric Mean	170.879, 236.142	161.754, 294.274	
	Median	220.500	236.500	
	Q25, Q75	145.000, 286.500	200.000, 276.000	
	Min, Max	71.40, 410.00	52.50, 452.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 5, T0 + 6 h	n	36	14	0
	Missing, n (%)	39 (52.0)	21 (60.0)	
	Geometric Mean (CV%)	211.367 (40.5814)	211.249 (61.3769)	
	95% CI of Geometric Mean	185.209, 241.219	152.409, 292.803	
	Median	222.000	237.000	
	Q25, Q75	160.500, 283.500	169.000, 282.000	
	Min, Max	76.50, 431.00	55.60, 473.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 5, T0 + 8 h	n	33	11	0
	Missing, n (%)	42 (56.0)	24 (68.6)	
	Geometric Mean (CV%)	203.507 (38.5494)	230.668 (63.1135)	
	95% CI of Geometric Mean	178.344, 232.221	156.331, 340.352	
	Median	208.000	249.000	
	Q25, Q75	159.000, 262.000	202.000, 356.000	
	Min, Max	87.20, 440.00	50.00, 434.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 5, T0 + 10 h	n	35	13	0
	Missing, n (%)	40 (53.3)	22 (62.9)	
	Geometric Mean (CV%)	218.901 (40.6870)	228.501 (60.3899)	
	95% CI of Geometric Mean	191.363, 250.403	163.135, 320.059	
	Median	217.000	257.000	
	Q25, Q75	154.000, 301.000	211.000, 304.000	
	Min, Max	96.60, 453.00	48.70, 481.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 5, T0 + 12 h	n	31	14	0
	Missing, n (%)	44 (58.7)	21 (60.0)	
	Geometric Mean (CV%)	225.576 (38.2011)	226.487 (58.7690)	
	95% CI of Geometric Mean	197.014, 258.278	165.371, 310.187	
	Median	237.000	254.000	
	Q25, Q75	163.000, 301.000	167.000, 293.000	
	Min, Max	96.70, 459.00	49.60, 473.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 5, T0 + 14 h	n	30	19	0
	Missing, n (%)	45 (60.0)	16 (45.7)	
	Geometric Mean (CV%)	194.680 (83.8621)	231.652 (51.2384)	
	95% CI of Geometric Mean	148.243, 255.663	183.555, 292.350	
	Median	232.500	262.000	
	Q25, Q75	154.000, 287.000	179.000, 301.000	
	Min, Max	7.80, 426.00	48.50, 458.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 5, T0 + 16 h	n	31	15	0
	Missing, n (%)	44 (58.7)	20 (57.1)	
	Geometric Mean (CV%)	215.873 (81.4283)	236.870 (56.1001)	
	95% CI of Geometric Mean	166.182, 280.422	177.298, 316.458	
	Median	256.000	251.000	
	Q25, Q75	194.000, 318.000	180.000, 307.000	
	Min, Max	7.53, 430.00	50.50, 473.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 5, 08:00 PM - 09:30 PM	n	0	0	21
	Missing, n (%)			3 (12.5)
	BLOQ, n(%)			1 (4.8)
	Geometric Mean (CV%)			4.902 (150.9529)
	95% CI of Geometric Mean			2.985, 8.050
	Median			5.120
	Q25, Q75			2.010, 13.900
	Min, Max			0.50, 27.10

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 6/Discharge Confinement, n		0	0	21
08:00 AM - 09:30 AM				
	Missing, n (%)			3 (12.5)
	BLOQ, n(%)			2 (9.5)
	Geometric Mean (CV%)			3.935 (156.4356)
	95% CI of Geometric Mean			2.371, 6.530
	Median			4.280
	Q25, Q75			1.850, 10.800
	Min, Max			0.50, 21.30

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 6/Discharge Confinement, n		26	14	0
T0 + 20 h				
	Missing, n (%)	49 (65.3)	21 (60.0)	
	Geometric Mean (CV%)	196.353 (91.2672)	216.514 (52.9442)	
	95% CI of Geometric Mean	143.380, 268.896	162.494, 288.493	
	Median	241.500	237.500	
	Q25, Q75	169.000, 272.000	182.000, 284.000	
	Min, Max	6.45, 430.00	50.90, 390.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
Cotinine (ng/mL)				
Day 6/Discharge Confinement, n		22	8	0
T0 + 24 h				
	Missing, n (%)	53 (70.7)	27 (77.1)	
	Geometric Mean (CV%)	185.625 (39.8436)	212.911 (29.8860)	
	95% CI of Geometric Mean	156.575, 220.065	166.725, 271.892	
	Median	195.500	249.000	
	Q25, Q75	146.000, 256.000	163.000, 266.500	
	Min, Max	82.30, 309.00	131.00, 276.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
Cotinine (ng/mL)				
Baseline, 08:00 PM - 09:30 PM	n	40	34	13
	Geometric Mean (CV%)	208.154 (61.1129)	230.151 (46.4263)	288.412 (45.0827)
	95% CI of Geometric Mean	173.836, 249.247	197.272, 268.511	222.395, 374.025
	Median	226.500	237.000	281.000
	Q25, Q75	142.500, 297.000	173.000, 316.000	206.000, 402.000
	Min, Max	21.00, 566.00	65.90, 450.00	139.00, 561.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
Cotinine (ng/mL)				
Day 30, 10:00 AM - 11:30 AM	n	39	33	13
	Missing, n (%)	1 (2.5)	1 (2.9)	0
	BLOQ, n(%)	0	0	2 (15.4)
	Geometric Mean (CV%)	214.110 (86.8384)	209.867 (63.2845)	40.967 (1666.4302)
	95% CI of Geometric Mean	167.919, 273.006	170.833, 257.821	9.766, 171.853
	Median	241.000	216.000	91.900
	Q25, Q75	181.000, 331.000	174.000, 340.000	18.600, 223.000
	Min, Max	5.67, 620.00	58.90, 557.00	0.50, 425.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
Cotinine (ng/mL)				
Baseline, 08:00 PM - 09:30 PM	n	39	35	12
	Geometric Mean (CV%)	204.033 (62.2991)	231.397 (45.8055)	228.159 (49.5925)
	95% CI of Geometric Mean	169.464, 245.653	199.181, 268.823	169.372, 307.350
	Median	223.000	252.000	226.500
	Q25, Q75	144.000, 282.000	173.000, 316.000	169.000, 314.500
	Min, Max	21.00, 566.00	65.90, 450.00	96.80, 476.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Appendix 15.3.3.3

Study ID: ZRHM-REXA-08-US

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Status: Final

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**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
Cotinine (ng/mL)				
Day 60, 10:00 AM - 11:30 AM	n	39	33	11
	Missing, n (%)	0	2 (5.7)	1 (8.3)
	BLOQ, n(%)	1 (2.6)	0	1 (9.1)
	Geometric Mean (CV%)	170.809 (120.0517)	195.797 (59.4837)	42.412 (1110.7605)
	95% CI of Geometric Mean	125.750, 232.013	161.082, 237.993	9.698, 185.466
	Median	189.000	208.000	79.000
	Q25, Q75	144.000, 300.000	156.000, 287.000	8.790, 247.000
	Min, Max	2.50, 627.00	49.50, 489.00	0.50, 805.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
Cotinine (ng/mL)				
Baseline, 08:00 PM - 09:30 PM	n	47	32	9
	Geometric Mean (CV%)	203.517 (59.9391)	237.046 (40.0713)	225.427 (46.9057)
	95% CI of Geometric Mean	172.963, 239.468	206.257, 272.431	160.006, 317.595
	Median	223.000	253.000	247.000
	Q25, Q75	143.000, 292.000	179.500, 309.000	199.000, 298.000
	Min, Max	21.00, 566.00	65.90, 450.00	96.80, 402.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.1 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
Cotinine (ng/mL)				
Day 90, 10:00 AM - 12:30 PM	n	47	31	9
	Missing, n (%)	0	1 (3.1)	0
	BLOQ, n(%)	1 (2.1)	0	2 (22.2)
	Geometric Mean (CV%)	176.217 (96.8706)	193.385 (71.7406)	27.927 (2078.4187)
	95% CI of Geometric Mean	138.774, 223.763	152.678, 244.946	4.202, 185.580
	Median	201.000	213.000	84.600
	Q25, Q75	154.000, 279.000	125.000, 323.000	10.500, 128.000
	Min, Max	2.50, 429.00	39.10, 470.00	0.50, 254.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Baseline, 08:00 PM - 09:30 PM	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	16.9479 (54.65827)	17.8985 (49.54886)	17.9870 (63.52173)
	95% CI of Geometric Mean	15.1026, 19.0187	15.4378, 20.7514	14.8541, 21.7806
	Median	17.5000	18.0000	21.7500
	Q25, Q75	13.2000, 23.3000	15.0000, 25.1000	13.4000, 26.5000
	Min, Max	1.580, 47.300	4.960, 43.700	4.300, 40.900

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 1, 08:00 PM - 09:30 PM	n	78	40	34
	Missing, n (%)	2 (2.5)	1 (2.4)	5 (12.8)
	BLOQ, n(%)	3 (3.8)	0	7 (20.6)
	Geometric Mean (CV%)	8.7454 (103.76760)	15.6366 (61.88042)	0.3620 (120.06308)
	95% CI of Geometric Mean	7.2122, 10.6045	13.0333, 18.7597	0.2603, 0.5034
	Median	10.7500	17.3000	0.3470
	Q25, Q75	6.6600, 15.8000	11.8500, 22.3500	0.2070, 0.6750
	Min, Max	0.500, 29.200	2.010, 42.700	0.100, 6.250

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 2, 08:00 PM - 09:30 PM	n	78	40	33
	Missing, n (%)	2 (2.5)	1 (2.4)	6 (15.4)
	BLOQ, n(%)	0	0	19 (57.6)
	Geometric Mean (CV%)	12.0646 (71.44205)	16.3253 (60.77603)	0.1662 (70.90331)
	95% CI of Geometric Mean	10.4384, 13.9442	13.6453, 19.5315	0.1325, 0.2085
	Median	13.4500	16.8000	0.1000
	Q25, Q75	8.7700, 18.7000	13.4500, 23.8000	0.1000, 0.2890
	Min, Max	1.100, 36.100	2.850, 40.300	0.100, 0.604

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 3, 08:00 PM - 09:30 PM	n	78	39	33
	Missing, n (%)	2 (2.5)	2 (4.9)	6 (15.4)
	BLOQ, n(%)	1 (1.3)	0	24 (72.7)
	Geometric Mean (CV%)	12.7969 (74.85539)	17.6224 (55.82127)	0.1332 (53.58069)
	95% CI of Geometric Mean	11.0101, 14.8737	14.8848, 20.8635	0.1114, 0.1593
	Median	13.5500	17.5000	0.1000
	Q25, Q75	9.5700, 21.0000	14.1000, 25.3000	0.1000, 0.2040
	Min, Max	0.500, 33.400	3.260, 39.700	0.100, 0.529

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 4, 08:00 PM - 09:30 PM	n	78	40	33
	Missing, n (%)	2 (2.5)	1 (2.4)	6 (15.4)
	BLOQ, n(%)	1 (1.3)	0	29 (87.9)
	Geometric Mean (CV%)	11.9700 (74.50142)	15.3631 (55.73108)	0.1121 (33.01975)
	95% CI of Geometric Mean	10.3046, 13.9046	13.0089, 18.1432	0.1000, 0.1257
	Median	13.8000	15.0000	0.1000
	Q25, Q75	9.7000, 18.0000	12.7000, 21.2500	0.1000, 0.1000
	Min, Max	0.500, 30.700	3.250, 37.500	0.100, 0.350

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 5, 15 min < T0	n	70	37	0
	Missing, n (%)	10 (12.5)	4 (9.8)	
	BLOQ, n(%)	18 (25.7)	5 (13.5)	
	Geometric Mean (CV%)	1.6024 (95.96648)	2.0390 (77.94131)	
	95% CI of Geometric Mean	1.3216, 1.9429	1.6205, 2.5656	
	Median	1.8800	2.2700	
	Q25, Q75	0.5000, 3.0200	1.6100, 3.2600	
	Min, Max	0.500, 5.800	0.500, 5.350	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 5, T0 + 2 h	n	32	18	0
	Missing, n (%)	48 (60.0)	23 (56.1)	
	BLOQ, n(%)	2 (6.3)	0	
	Geometric Mean (CV%)	8.5208 (113.34118)	12.5053 (54.63222)	
	95% CI of Geometric Mean	6.1398, 11.8251	9.6988, 16.1239	
	Median	9.7100	12.3500	
	Q25, Q75	6.6300, 15.4500	8.0700, 17.7000	
	Min, Max	0.500, 21.800	5.080, 31.200	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 5, T0 + 4 h	n	30	16	0
	Missing, n (%)	50 (62.5)	25 (61.0)	
	BLOQ, n(%)	1 (3.3)	0	
	Geometric Mean (CV%)	10.7277 (99.30823)	12.8695 (66.64807)	
	95% CI of Geometric Mean	7.8734, 14.6166	9.3167, 17.7773	
	Median	12.3500	13.8000	
	Q25, Q75	9.7900, 15.6000	9.2750, 19.1500	
	Min, Max	0.500, 27.100	3.060, 28.700	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 5, T0 + 6 h	n	38	17	0
	Missing, n (%)	42 (52.5)	24 (58.5)	
	BLOQ, n(%)	1 (2.6)	0	
	Geometric Mean (CV%)	11.7148 (86.38161)	14.8628 (63.77230)	
	95% CI of Geometric Mean	9.1655, 14.9732	11.0068, 20.0697	
	Median	13.5500	17.4000	
	Q25, Q75	9.4000, 18.0000	14.7000, 20.9000	
	Min, Max	0.500, 36.200	3.170, 28.200	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 5, T0 + 8 h	n	36	14	0
	Missing, n (%)	44 (55.0)	27 (65.9)	
	BLOQ, n(%)	2 (5.6)	0	
	Geometric Mean (CV%)	12.0677 (115.33343)	14.7587 (53.72815)	
	95% CI of Geometric Mean	8.8403, 16.4732	11.0348, 19.7391	
	Median	14.7500	15.4000	
	Q25, Q75	8.9350, 20.7000	12.7000, 20.5000	
	Min, Max	0.500, 29.400	3.470, 30.000	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 5, T0 + 10 h	n	37	16	0
	Missing, n (%)	43 (53.8)	25 (61.0)	
	BLOQ, n(%)	1 (2.7)	0	
	Geometric Mean (CV%)	14.4148 (88.30363)	15.8512 (64.22074)	
	95% CI of Geometric Mean	11.1909, 18.5674	11.5897, 21.6797	
	Median	17.0000	17.5500	
	Q25, Q75	11.7000, 23.8000	11.5500, 23.0500	
	Min, Max	0.500, 32.600	5.010, 37.700	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 5, T0 + 12 h	n	34	18	0
	Missing, n (%)	46 (57.5)	23 (56.1)	
	BLOQ, n(%)	2 (5.9)	0	
	Geometric Mean (CV%)	13.0464 (132.11828)	14.7423 (61.02346)	
	95% CI of Geometric Mean	9.1876, 18.5258	11.1443, 19.5019	
	Median	18.4500	17.9000	
	Q25, Q75	10.5000, 23.4000	10.2000, 21.3000	
	Min, Max	0.500, 33.300	3.240, 32.500	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 5, T0 + 14 h	n	31	20	0
	Missing, n (%)	49 (61.3)	21 (51.2)	
	BLOQ, n(%)	1 (3.2)	0	
	Geometric Mean (CV%)	14.2628 (122.22416)	16.9278 (51.22467)	
	95% CI of Geometric Mean	10.0443, 20.2530	13.5047, 21.2186	
	Median	19.6000	18.6500	
	Q25, Q75	14.1000, 24.9000	11.3500, 24.3000	
	Min, Max	0.500, 36.500	6.650, 34.100	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 5, T0 + 16 h	n	33	17	0
	Missing, n (%)	47 (58.8)	24 (58.5)	
	BLOQ, n(%)	2 (6.1)	0	
	Geometric Mean (CV%)	18.5459 (134.10489)	20.4472 (44.27207)	
	95% CI of Geometric Mean	12.9429, 26.5744	16.4499, 25.4157	
	Median	24.7000	18.8000	
	Q25, Q75	17.9000, 30.3000	15.5000, 26.7000	
	Min, Max	0.500, 44.400	7.670, 38.400	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 5, 08:00 PM - 09:30 PM	n	0	0	33
	Missing, n (%)			6 (15.4)
	BLOQ, n(%)			32 (97.0)
	Geometric Mean (CV%)			0.1043 (24.71391)
	95% CI of Geometric Mean			0.0957, 0.1138
	Median			0.1000
	Q25, Q75			0.1000, 0.1000
	Min, Max			0.100, 0.405

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 6/Discharge Confinement, n		0	0	33
08:00 AM - 09:30 AM				
	Missing, n (%)			6 (15.4)
	BLOQ, n(%)			32 (97.0)
	Geometric Mean (CV%)			0.1041 (23.50896)
	95% CI of Geometric Mean			0.0958, 0.1131
	Median			0.1000
	Q25, Q75			0.1000, 0.1000
	Min, Max			0.100, 0.379

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 6/Discharge Confinement, n		28	16	0
T0 + 20 h				
	Missing, n (%)	52 (65.0)	25 (61.0)	
	BLOQ, n(%)	2 (7.1)	0	
	Geometric Mean (CV%)	6.0493 (110.18566)	6.5503 (44.95089)	
	95% CI of Geometric Mean	4.2811, 8.5475	5.2117, 8.2327	
	Median	6.6250	7.1800	
	Q25, Q75	4.0350, 12.1500	4.6650, 8.7050	
	Min, Max	0.500, 18.500	3.220, 14.300	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 6/Discharge Confinement, n		28	9	0
T0 + 24 h				
	Missing, n (%)	52 (65.0)	32 (78.0)	
	BLOQ, n(%)	8 (28.6)	2 (22.2)	
	Geometric Mean (CV%)	1.7022 (115.47779)	2.1392 (106.71528)	
	95% CI of Geometric Mean	1.1912, 2.4324	1.0944, 4.1815	
	Median	2.3500	3.5500	
	Q25, Q75	0.5000, 3.4750	1.8600, 3.8300	
	Min, Max	0.500, 6.640	0.500, 4.530	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 30, 10:00 AM - 11:30 AM	n	76	39	33
	Missing, n (%)	4 (5.0)	2 (4.9)	6 (15.4)
	BLOQ, n(%)	1 (1.3)	0	7 (21.2)
	Geometric Mean (CV%)	10.5749 (87.38996)	13.1671 (48.91318)	1.1904 (401.17540)
	95% CI of Geometric Mean	8.9026, 12.5612	11.3314, 15.3001	0.6550, 2.1636
	Median	11.7000	14.2000	1.2600
	Q25, Q75	8.5300, 16.0000	10.5000, 18.9000	0.2820, 5.6700
	Min, Max	0.500, 33.000	3.170, 28.600	0.100, 12.100

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 60, 10:00 AM - 11:30 AM	n	74	37	31
	Missing, n (%)	6 (7.5)	4 (9.8)	8 (20.5)
	BLOQ, n(%)	1 (1.4)	0	6 (19.4)
	Geometric Mean (CV%)	11.4299 (75.64598)	14.1981 (53.67063)	2.1864 (418.51641)
	95% CI of Geometric Mean	9.7804, 13.3576	12.0053, 16.7913	1.1683, 4.0915
	Median	12.3000	14.1000	3.1400
	Q25, Q75	9.0900, 17.1000	11.7000, 19.9000	1.5400, 8.4200
	Min, Max	0.500, 34.300	3.740, 33.900	0.100, 19.300

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Nicotine (ng/mL)				
Day 90, 10:00 AM - 12:30 PM	n	73	35	31
	Missing, n (%)	7 (8.8)	6 (14.6)	8 (20.5)
	BLOQ, n(%)	1 (1.4)	0	2 (6.5)
	Geometric Mean (CV%)	9.1226 (80.88896)	12.7443 (54.85045)	2.7537 (232.86973)
	95% CI of Geometric Mean	7.7308, 10.7650	10.6857, 15.1995	1.6698, 4.5412
	Median	8.9700	13.9000	3.2300
	Q25, Q75	6.7700, 15.4000	8.4400, 19.1000	1.8500, 6.6100
	Min, Max	0.500, 27.900	3.510, 28.000	0.100, 18.400

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Baseline, 08:00 PM - 09:30 PM	n	78	41	38
	Missing, n (%)	2 (2.5)	0	1 (2.6)
	Geometric Mean (CV%)	213.089 (50.8141)	231.490 (43.2367)	257.229 (51.0653)
	95% CI of Geometric Mean	191.264, 237.405	203.134, 263.804	219.585, 301.326
	Median	224.000	241.000	277.000
	Q25, Q75	153.000, 275.000	186.000, 302.000	202.000, 374.000
	Min, Max	21.00, 605.00	65.90, 450.00	87.40, 561.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 1, 08:00 PM - 09:30 PM	n	78	40	34
	Missing, n (%)	2 (2.5)	1 (2.4)	5 (12.8)
	Geometric Mean (CV%)	172.217 (57.1246)	223.256 (45.3963)	114.849 (59.4828)
	95% CI of Geometric Mean	152.770, 194.139	194.392, 256.405	94.781, 139.165
	Median	182.500	235.500	107.150
	Q25, Q75	130.000, 242.000	174.500, 292.500	77.600, 187.000
	Min, Max	20.50, 475.00	56.60, 456.00	43.10, 329.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 2, 08:00 PM - 09:30 PM	n	78	40	33
	Missing, n (%)	2 (2.5)	1 (2.4)	6 (15.4)
	Geometric Mean (CV%)	166.246 (61.7815)	224.265 (48.6861)	48.929 (83.4343)
	95% CI of Geometric Mean	146.242, 188.986	193.509, 259.909	37.811, 63.314
	Median	181.500	232.000	48.400
	Q25, Q75	128.000, 248.000	170.000, 302.000	28.500, 75.400
	Min, Max	23.90, 451.00	48.20, 455.00	15.10, 173.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 3, 08:00 PM - 09:30 PM	n	78	39	33
	Missing, n (%)	2 (2.5)	2 (4.9)	6 (15.4)
	Geometric Mean (CV%)	182.089 (61.6785)	234.473 (48.8132)	21.140 (106.0381)
	95% CI of Geometric Mean	160.208, 206.957	201.841, 272.381	15.539, 28.760
	Median	195.000	242.000	19.700
	Q25, Q75	149.000, 257.000	174.000, 316.000	10.200, 33.100
	Min, Max	15.90, 493.00	40.40, 466.00	3.48, 92.90

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 4, 08:00 PM - 09:30 PM	n	78	40	33
	Missing, n (%)	2 (2.5)	1 (2.4)	6 (15.4)
	Geometric Mean (CV%)	186.865 (63.0215)	235.451 (44.1415)	9.095 (130.1715)
	95% CI of Geometric Mean	164.021, 212.891	205.729, 269.465	6.390, 12.946
	Median	205.500	246.500	9.430
	Q25, Q75	148.000, 266.000	185.000, 301.000	3.730, 17.200
	Min, Max	8.54, 459.00	51.80, 456.00	1.32, 54.80

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 5, 15 min < T0	n	69	36	0
	Missing, n (%)	11 (13.8)	5 (12.2)	
	Geometric Mean (CV%)	163.995 (69.3086)	217.082 (46.7503)	
	95% CI of Geometric Mean	141.086, 190.623	186.763, 252.322	
	Median	175.000	229.000	
	Q25, Q75	130.000, 238.000	165.000, 287.500	
	Min, Max	6.88, 462.00	53.00, 452.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 5, T0 + 2 h	n	30	18	0
	Missing, n (%)	50 (62.5)	23 (56.1)	
	Geometric Mean (CV%)	185.865 (41.8111)	225.607 (48.5312)	
	95% CI of Geometric Mean	159.994, 215.919	179.485, 283.579	
	Median	196.500	248.000	
	Q25, Q75	137.000, 247.000	217.000, 266.000	
	Min, Max	63.90, 385.00	51.70, 437.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 5, T0 + 4 h	n	29	16	0
	Missing, n (%)	51 (63.8)	25 (61.0)	
	Geometric Mean (CV%)	200.847 (42.7384)	227.365 (53.0109)	
	95% CI of Geometric Mean	171.871, 234.709	174.404, 296.408	
	Median	218.000	250.500	
	Q25, Q75	148.000, 267.000	209.500, 305.000	
	Min, Max	71.40, 410.00	52.50, 452.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 5, T0 + 6 h	n	37	17	0
	Missing, n (%)	43 (53.8)	24 (58.5)	
	Geometric Mean (CV%)	211.464 (39.9715)	223.635 (56.6396)	
	95% CI of Geometric Mean	185.989, 240.428	170.512, 293.309	
	Median	221.000	260.000	
	Q25, Q75	164.000, 275.000	205.000, 282.000	
	Min, Max	76.50, 431.00	55.60, 473.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 5, T0 + 8 h	n	34	14	0
	Missing, n (%)	46 (57.5)	27 (65.9)	
	Geometric Mean (CV%)	203.343 (37.9235)	242.995 (55.8549)	
	95% CI of Geometric Mean	178.929, 231.088	179.858, 328.294	
	Median	206.500	255.000	
	Q25, Q75	159.000, 262.000	232.000, 342.000	
	Min, Max	87.20, 440.00	50.00, 434.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 5, T0 + 10 h	n	36	16	0
	Missing, n (%)	44 (55.0)	25 (61.0)	
	Geometric Mean (CV%)	218.649 (40.0636)	241.474 (55.0670)	
	95% CI of Geometric Mean	191.890, 249.140	183.558, 317.664	
	Median	217.000	260.500	
	Q25, Q75	157.000, 289.500	217.000, 328.500	
	Min, Max	96.60, 453.00	48.70, 481.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 5, T0 + 12 h	n	32	18	0
	Missing, n (%)	48 (60.0)	23 (56.1)	
	Geometric Mean (CV%)	225.270 (37.5467)	233.706 (53.7126)	
	95% CI of Geometric Mean	197.624, 256.784	181.943, 300.196	
	Median	235.500	264.500	
	Q25, Q75	173.500, 294.500	167.000, 293.000	
	Min, Max	96.70, 459.00	49.60, 473.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 5, T0 + 14 h	n	31	20	0
	Missing, n (%)	49 (61.3)	21 (51.2)	
	Geometric Mean (CV%)	195.156 (82.0747)	233.647 (49.8977)	
	95% CI of Geometric Mean	149.990, 253.923	187.379, 291.339	
	Median	230.000	263.000	
	Q25, Q75	154.000, 287.000	179.500, 296.500	
	Min, Max	7.80, 426.00	48.50, 458.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 5, T0 + 16 h	n	32	17	0
	Missing, n (%)	48 (60.0)	24 (58.5)	
	Geometric Mean (CV%)	215.939 (79.7494)	241.679 (52.4036)	
	95% CI of Geometric Mean	167.676, 278.092	187.606, 311.337	
	Median	255.000	264.000	
	Q25, Q75	197.000, 308.000	205.000, 302.000	
	Min, Max	7.53, 430.00	50.50, 473.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 5, 08:00 PM - 09:30 PM	n	0	0	31
	Missing, n (%)			8 (20.5)
	BLOQ, n(%)			2 (6.5)
	Geometric Mean (CV%)			4.229 (157.9087)
	95% CI of Geometric Mean			2.805, 6.374
	Median			4.430
	Q25, Q75			1.650, 10.700
	Min, Max			0.50, 29.90

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 6/Discharge Confinement, n		0	0	29
08:00 AM - 09:30 AM				
	Missing, n (%)			10 (25.6)
	BLOQ, n(%)			3 (10.3)
	Geometric Mean (CV%)			3.431 (165.5682)
	95% CI of Geometric Mean			2.216, 5.312
	Median			2.780
	Q25, Q75			1.510, 8.340
	Min, Max			0.50, 24.90

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 6/Discharge Confinement, n		27	16	0
T0 + 20 h				
	Missing, n (%)	53 (66.3)	25 (61.0)	
	Geometric Mean (CV%)	198.117 (89.1415)	223.735 (49.8811)	
	95% CI of Geometric Mean	146.400, 268.103	174.040, 287.621	
	Median	246.000	261.500	
	Q25, Q75	169.000, 272.000	185.500, 283.500	
	Min, Max	6.45, 430.00	50.90, 390.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 6/Discharge Confinement, n		23	9	0
T0 + 24 h				
	Missing, n (%)	57 (71.3)	32 (78.0)	
	Geometric Mean (CV%)	187.148 (39.0878)	217.316 (28.6017)	
	95% CI of Geometric Mean	158.990, 220.293	175.178, 269.589	
	Median	209.000	252.000	
	Q25, Q75	146.000, 256.000	166.000, 257.000	
	Min, Max	82.30, 309.00	131.00, 276.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 30, 10:00 AM - 11:30 AM	n	76	39	33
	Missing, n (%)	4 (5.0)	2 (4.9)	6 (15.4)
	BLOQ, n(%)	0	0	2 (6.1)
	Geometric Mean (CV%)	212.303 (72.6611)	215.635 (59.6355)	83.950 (499.1762)
	95% CI of Geometric Mean	182.953, 246.362	180.327, 257.855	44.278, 159.165
	Median	243.000	220.000	160.000
	Q25, Q75	165.500, 308.500	174.000, 340.000	37.400, 294.000
	Min, Max	5.67, 620.00	58.90, 557.00	0.50, 514.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 60, 10:00 AM - 11:30 AM	n	74	37	31
	Missing, n (%)	6 (7.5)	4 (9.8)	8 (20.5)
	BLOQ, n(%)	1 (1.4)	0	1 (3.2)
	Geometric Mean (CV%)	193.597 (92.1233)	202.558 (57.9414)	117.094 (314.3023)
	95% CI of Geometric Mean	161.445, 232.151	169.294, 242.357	66.439, 206.368
	Median	221.000	219.000	157.000
	Q25, Q75	150.000, 304.000	157.000, 299.000	94.200, 277.000
	Min, Max	2.50, 627.00	49.50, 489.00	0.50, 805.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.19.2 Descriptive Statistics of Plasma Nicotine and Cotinine Concentrations (ng/mL) - FAS****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
Cotinine (ng/mL)				
Day 90, 10:00 AM - 12:30 PM	n	73	35	31
	Missing, n (%)	7 (8.8)	6 (14.6)	8 (20.5)
	BLOQ, n(%)	1 (1.4)	0	2 (6.5)
	Geometric Mean (CV%)	193.657 (81.5362)	201.372 (68.9649)	130.037 (406.9113)
	95% CI of Geometric Mean	163.942, 228.758	162.533, 249.491	69.888, 241.951
	Median	213.000	231.000	220.000
	Q25, Q75	164.000, 292.000	128.000, 325.000	99.800, 322.000
	Min, Max	2.50, 491.00	39.10, 470.00	0.50, 788.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Nicotine (ng/mL)				
Day 1	n	74	34	
	Geometric LS Mean (CV%)	8.81	14.88	59.18 (67.41)
	95% CI	7.63, 10.17	12.07, 18.35	46.03, 76.09
Day 2	n	74	34	
	Geometric LS Mean (CV%)	11.75	15.27	76.94 (53.28)
	95% CI	10.45, 13.21	12.87, 18.13	62.67, 94.47
Day 3	n	74	33	
	Geometric LS Mean (CV%)	12.60	16.57	76.03 (54.49)
	95% CI	11.18, 14.20	13.87, 19.79	61.54, 93.94

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Nicotine (ng/mL)				
Day 4	n	74	34	
	Geometric LS Mean (CV%)	11.85	14.52	81.61 (51.45)
	95% CI	10.58, 13.27	12.30, 17.14	66.89, 99.57
Day 5	n	69	34	
	Geometric LS Mean (CV%)	14.07	17.65	79.69 (48.77)
	95% CI	12.58, 15.73	15.06, 20.69	65.75, 96.57
Day 30	n	39	33	
	Geometric LS Mean (CV%)	11.99	13.05	91.90 (82.18)
	95% CI	9.49, 15.16	10.15, 16.79	65.28, 129.36

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Nicotine (ng/mL)				
Day 60	n	39	33	
	Geometric LS Mean (CV%)	11.38	13.17	86.41 (106.41)
	95% CI	8.56, 15.13	9.68, 17.90	56.84, 131.37
Day 90	n	47	31	
	Geometric LS Mean (CV%)	8.93	12.40	71.98 (84.34)
	95% CI	7.18, 11.09	9.51, 16.17	51.13, 101.33

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Cotinine (ng/mL)				
Day 1	n	74	34	
	Geometric LS Mean (CV%)	179.48	216.91	82.74 (25.35)
	95% CI	169.28, 190.29	199.17, 236.22	74.67, 91.69
Day 2	n	74	34	
	Geometric LS Mean (CV%)	172.00	211.27	81.41 (32.49)
	95% CI	159.69, 185.26	189.59, 235.43	71.47, 92.74
Day 3	n	74	33	
	Geometric LS Mean (CV%)	187.97	222.25	84.58 (38.37)
	95% CI	172.33, 205.04	195.37, 252.84	72.51, 98.65

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Cotinine (ng/mL)				
Day 4	n	74	34	
	Geometric LS Mean (CV%)	193.27	223.95	86.30 (44.02)
	95% CI	175.11, 213.30	193.96, 258.59	72.59, 102.60
Day 5	n	70	34	
	Geometric LS Mean (CV%)	192.05	228.36	84.10 (38.61)
	95% CI	175.60, 210.04	200.89, 259.59	72.01, 98.22
Day 30	n	39	33	
	Geometric LS Mean (CV%)	233.17	207.23	112.52 (125.99)
	95% CI	169.48, 320.79	147.36, 291.42	70.76, 178.90

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.20.1 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Cotinine (ng/mL)				
Day 60	n	39	33	
	Geometric LS Mean (CV%)	188.85	177.84	106.19 (122.65)
	95% CI	137.80, 258.83	126.86, 249.31	66.77, 168.88
Day 90	n	47	31	
	Geometric LS Mean (CV%)	183.36	178.63	102.65 (120.11)
	95% CI	138.43, 242.87	126.85, 251.54	65.82, 160.08

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Nicotine (ng/mL)				
Day 1	n	78	40	
	Geometric LS Mean (CV%)	8.84	14.86	59.45 (67.98)
	95% CI	7.68, 10.17	12.24, 18.05	46.90, 75.37
Day 2	n	78	40	
	Geometric LS Mean (CV%)	12.01	15.56	77.17 (51.80)
	95% CI	10.75, 13.41	13.34, 18.14	63.96, 93.10
Day 3	n	78	39	
	Geometric LS Mean (CV%)	12.72	16.91	75.23 (51.87)
	95% CI	11.38, 14.21	14.46, 19.76	62.25, 90.92

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Nicotine (ng/mL)				
Day 4	n	78	40	
	Geometric LS Mean (CV%)	12.01	14.85	80.87 (49.58)
	95% CI	10.80, 13.36	12.81, 17.22	67.51, 96.86
Day 5	n	73	40	
	Geometric LS Mean (CV%)	14.10	17.52	80.47 (47.20)
	95% CI	12.69, 15.66	15.20, 20.19	67.54, 95.88
Day 30	n	76	39	
	Geometric LS Mean (CV%)	10.93	12.87	84.95 (106.08)
	95% CI	8.95, 13.35	9.76, 16.97	60.55, 119.17

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Nicotine (ng/mL)				
Day 60	n	74	37	
	Geometric LS Mean (CV%)	11.68	13.77	84.81 (111.84)
	95% CI	9.48, 14.39	10.24, 18.51	59.18, 121.54
Day 90	n	73	35	
	Geometric LS Mean (CV%)	9.40	12.68	74.08 (93.49)
	95% CI	7.80, 11.31	9.71, 16.57	53.65, 102.30

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Cotinine (ng/mL)				
Day 1	n	78	40	
	Geometric LS Mean (CV%)	182.27	217.42	83.84 (24.74)
	95% CI	172.43, 192.68	201.39, 234.72	76.31, 92.10
Day 2	n	78	40	
	Geometric LS Mean (CV%)	175.03	216.15	80.97 (33.33)
	95% CI	162.56, 188.45	195.19, 239.36	71.45, 91.77
Day 3	n	78	39	
	Geometric LS Mean (CV%)	190.79	225.48	84.61 (40.60)
	95% CI	174.56, 208.52	199.07, 255.38	72.69, 98.49

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Cotinine (ng/mL)				
Day 4	n	78	40	
	Geometric LS Mean (CV%)	195.77	225.88	86.67 (46.93)
	95% CI	176.87, 216.70	196.32, 259.88	72.97, 102.95
Day 5	n	74	40	
	Geometric LS Mean (CV%)	194.29	229.80	84.54 (37.05)
	95% CI	178.71, 211.21	205.15, 257.42	73.49, 97.27
Day 30	n	76	39	
	Geometric LS Mean (CV%)	224.83	209.85	107.14 (108.62)
	95% CI	183.40, 275.61	158.49, 277.86	75.90, 151.23

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.20.2 Analysis of Plasma Nicotine and Cotinine Concentrations (ng/mL) over the 90 Days - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Cotinine (ng/mL)				
Day 60	n	74	37	
	Geometric LS Mean (CV%)	208.36	190.47	109.39 (103.12)
	95% CI	170.80, 254.18	144.04, 251.87	77.72, 153.96
Day 90	n	73	35	
	Geometric LS Mean (CV%)	208.43	194.36	107.24 (110.20)
	95% CI	169.00, 257.06	143.99, 262.34	74.48, 154.40

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.3.3

Study ID: ZRHM-REXA-08-US

Program: t_anl_nc.sas

Status: Final

26APR16

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**Table 15.2.4.21.1 Descriptive Statistics of Plasma Nicotine and Cotinine PK Parameters on Day 5 - PP Set**

Variable	Statistic	THSm2.2 (N=75)	mCC (N=35)
Nicotine			
C _{avg} (ng/mL)	n	74	34
	Geometric Mean (CV%)	11.083 (61.8249)	12.955 (41.0095)
	95% CI of Geometric Mean	9.714, 12.645	11.289, 14.866
	Median	12.304	13.812
	Q25, Q75	8.896, 16.141	11.104, 16.018
	Min, Max	1.13, 24.45	4.65, 26.08
	Mean (SD)	12.523 (5.3205)	13.877 (4.9414)
C _{peak} (ng/mL)	n	74	34
	Geometric Mean (CV%)	20.909 (53.2911)	23.271 (41.4589)
	95% CI of Geometric Mean	18.621, 23.477	20.251, 26.740
	Median	23.050	24.950
	Q25, Q75	15.800, 29.800	18.400, 31.500
	Min, Max	2.34, 47.40	7.67, 43.40
	Mean (SD)	23.173 (9.5245)	24.923 (8.5986)
t _{peak} (h) ⁽¹⁾	n	74	34
	Median	15.933	14.067
	Q25, Q75	11.967, 16.000	9.883, 16.000
	Min, Max	1.97, 16.25	1.82, 16.25

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.3.4

Study ID: ZRHM-REXA-08-US Program: t_desp_nc_pk.sas Status: Final

30NOV15

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**Table 15.2.4.21.1 Descriptive Statistics of Plasma Nicotine and Cotinine PK Parameters on Day 5 - PP Set**

Variable	Statistic	THSm2.2 (N=75)	mCC (N=35)
Cotinine			
C _{avg} (ng/mL)	n	74	34
	Geometric Mean (CV%)	190.964 (59.2347)	233.512 (45.0440)
	95% CI of Geometric Mean	168.179, 216.837	200.992, 271.294
	Median	211.293	254.774
	Q25, Q75	149.674, 274.912	185.433, 291.030
	Min, Max	16.18, 438.03	50.87, 464.33
	Mean (SD)	214.264 (90.5261)	252.247 (92.7937)
C _{peak} (ng/mL)	n	74	34
	Geometric Mean (CV%)	219.75 (48.841)	256.44 (44.049)
	95% CI of Geometric Mean	197.41, 244.61	221.39, 297.03
	Median	247.00	277.00
	Q25, Q75	167.00, 307.00	206.00, 318.00
	Min, Max	30.7, 476.0	55.6, 484.0
	Mean (SD)	240.87 (96.711)	275.99 (98.160)
t _{peak} (h) ⁽¹⁾	n	74	34
	Median	16.008	16.000
	Q25, Q75	15.917, 19.933	15.433, 19.950
	Min, Max	0.00, 24.10	0.00, 20.03

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.3.4

Study ID: ZRHM-REXA-08-US

Program: t_desp_nc_pk.sas

Status: Final

30NOV15

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**Table 15.2.4.21.2 Descriptive Statistics of Plasma Nicotine and Cotinine PK Parameters on Day 5 - FAS**

Variable	Statistic	THSm2.2 (N=80)	mCC (N=41)
Nicotine			
C _{avg} (ng/mL)	n	78	40
	Geometric Mean (CV%)	11.132 (60.2186)	13.165 (38.4531)
	95% CI of Geometric Mean	9.819, 12.620	11.690, 14.825
	Median	12.304	13.812
	Q25, Q75	8.896, 16.040	11.420, 16.082
	Min, Max	1.13, 24.45	4.65, 26.08
	Mean (SD)	12.512 (5.2096)	13.993 (4.6728)
C _{peak} (ng/mL)	n	78	40
	Geometric Mean (CV%)	20.907 (52.1190)	23.545 (38.5793)
	95% CI of Geometric Mean	18.719, 23.351	20.900, 26.524
	Median	23.000	24.500
	Q25, Q75	15.800, 29.800	20.450, 30.700
	Min, Max	2.34, 47.40	7.67, 43.40
	Mean (SD)	23.091 (9.3721)	25.007 (8.0840)
t _{peak} (h) ⁽¹⁾	n	78	40
	Median	15.933	13.983
	Q25, Q75	11.933, 16.000	9.917, 15.975
	Min, Max	1.97, 16.25	1.82, 16.25

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.3.4

Study ID: ZRHM-REXA-08-US

Program: t_desp_nc_pk.sas

Status: Final

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**Table 15.2.4.21.2 Descriptive Statistics of Plasma Nicotine and Cotinine PK Parameters on Day 5 - FAS**

Variable	Statistic	THSm2.2 (N=80)	mCC (N=41)
Cotinine			
C _{avg} (ng/mL)	n	78	40
	Geometric Mean (CV%)	191.563 (57.5101)	236.402 (42.7974)
	95% CI of Geometric Mean	169.812, 216.100	207.343, 269.535
	Median	211.293	260.321
	Q25, Q75	150.951, 272.438	185.712, 291.947
	Min, Max	16.18, 438.03	50.87, 464.33
	Mean (SD)	213.727 (88.2657)	253.756 (89.2643)
C _{peak} (ng/mL)	n	78	40
	Geometric Mean (CV%)	219.90 (47.505)	259.80 (41.417)
	95% CI of Geometric Mean	198.63, 243.44	228.75, 295.06
	Median	246.00	280.00
	Q25, Q75	167.00, 304.00	209.50, 324.50
	Min, Max	30.7, 476.0	55.6, 484.0
	Mean (SD)	240.01 (94.402)	277.54 (93.494)
t _{peak} (h) ⁽¹⁾	n	78	40
	Median	16.008	16.000
	Q25, Q75	15.833, 19.933	14.708, 19.950
	Min, Max	0.00, 24.10	0.00, 20.03

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.3.4

Study ID: ZRHM-REXA-08-US

Program: t_desp_nc_pk.sas

Status: Final

30NOV15

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**Table 15.2.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Nicotine				
C _{avg} (ng/mL)	n	74	34	
	Geometric LS Mean (CV%)	11.05	12.97	85.20 (56.00)
	95% CI	9.77, 12.50	10.84, 15.52	68.74, 105.61
C _{peak} (ng/mL)	n	74	34	
	Geometric LS Mean (CV%)	20.96	23.43	89.46 (49.68)
	95% CI	18.77, 23.41	19.94, 27.53	73.75, 108.51
Variable	Statistic	THSm2.2 - mCC Difference (h)		
t _{peak} (h) ⁽¹⁾	n	74	34	
	Median	14.97	13.03	0.18
	95% CI			0.00, 1.94

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed Day 5 values with study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

(1): For t_{peak} the medians for each product and the median difference and 95% confidence interval between THS 2.2 Menthol and mCC is reported. The 95% CI is based on the Hodges-Lehmann estimate.

**Table 15.2.4.22.1 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Cotinine				
C _{avg} (ng/mL)	n	74	34	
	Geometric LS Mean (CV%)	189.00	231.72	81.57 (55.32)
	95% CI	167.40, 213.40	194.10, 276.62	65.95, 100.87
C _{peak} (ng/mL)	n	74	34	
	Geometric LS Mean (CV%)	217.64	254.96	85.36 (47.36)
	95% CI	195.81, 241.90	218.52, 297.47	70.95, 102.70
Variable	Statistic	THSm2.2 - mCC Difference (h)		
t _{peak} (h) ⁽¹⁾	n	74	34	
	Median	16.07	16.03	0.03
	95% CI			-0.10, 1.62

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed Day 5 values with study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

(1): For t_{peak} the medians for each product and the median difference and 95% confidence interval between THS 2.2 Menthol and mCC is reported. The 95% CI is based on the Hodges-Lehmann estimate.

**Table 15.2.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Nicotine				
C _{avg} (ng/mL)	n	78	40	
	Geometric LS Mean (CV%)	11.06	13.06	84.65 (53.55)
	95% CI	9.86, 12.40	11.14, 15.31	69.76, 102.72
C _{peak} (ng/mL)	n	78	40	
	Geometric LS Mean (CV%)	20.87	23.47	88.94 (47.73)
	95% CI	18.82, 23.14	20.34, 27.07	74.69, 105.90
Variable	Statistic	THSm2.2 - mCC Difference (h)		
t _{peak} (h) ⁽¹⁾	n	78	40	
	Median	14.93	12.95	0.24
	95% CI			0.00, 2.00

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed Day 5 values with study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

(1): For t_{peak} the medians for each product and the median difference and 95% confidence interval between THS 2.2 Menthol and mCC is reported. The 95% CI is based on the Hodges-Lehmann estimate.

**Table 15.2.4.22.2 Analysis of Plasma Nicotine and Cotinine Concentration PK Parameters on Day 5 - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 : mCC Ratio (%)
Cotinine				
C _{avg} (ng/mL)	n	78	40	
	Geometric LS Mean (CV%)	189.24	233.52	81.04 (52.89)
	95% CI	169.01, 211.89	199.66, 273.13	66.92, 98.13
C _{peak} (ng/mL)	n	78	40	
	Geometric LS Mean (CV%)	217.25	256.56	84.68 (45.32)
	95% CI	196.90, 239.71	223.86, 294.03	71.69, 100.03
Variable	Statistic	THSm2.2 - mCC Difference (h)		
t _{peak} (h) ⁽¹⁾	n	78	40	
	Median	16.04	16.00	0.03
	95% CI			-0.09, 1.65

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed Day 5 values with study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

(1): For t_{peak} the medians for each product and the median difference and 95% confidence interval between THS 2.2 Menthol and mCC is reported. The 95% CI is based on the Hodges-Lehmann estimate.

**Table 15.2.4.23.1 Descriptive Statistics of CYP1A2 Activity (%) PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		34		23	
	Missing, n(%)	1(1.3)		1(2.9)		1(4.2)	
	Geometric Mean (CV%)	117.595 (32.7669)		121.602 (31.6944)		114.031 (39.5995)	
	95% CI of Geometric Mean	109.208, 126.626		109.158, 135.464		96.682, 134.494	
	Median	116.810		122.390		119.520	
	Q25, Q75	94.940, 143.380		105.140, 142.250		104.550, 146.600	
	Min, Max	55.68, 237.58		61.58, 202.77		43.37, 260.48	
	Mean (SD)	123.602 (39.6424)		127.184 (37.9314)		121.655 (43.8439)	
	95% CI of Mean	114.417, 132.787		113.949, 140.419		102.695, 140.615	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.23.1 Descriptive Statistics of CYP1A2 Activity (%) PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	74	74	35	34	23	23
	Missing, n(%)	1(1.3)	1(1.3)	0	1(2.9)	1(4.2)	1(4.2)
	Geometric Mean (CV%)	76.699 (38.7405)		123.555 (27.3614)		73.436 (47.9527)	
	95% CI of Geometric Mean	70.333, 83.641		112.661, 135.503		60.321, 89.403	
	Median	79.495	-33.716	121.860	3.281	74.290	-35.519
	Q25, Q75	60.870, 95.470	-43.463, -26.490	108.430, 150.670	-7.111, 10.482	54.390, 100.020	-47.977, -21.854
	Min, Max	27.39, 175.20	-69.22, 24.98	70.24, 202.77	-17.97, 39.24	21.37, 181.73	-54.92, -19.38
	Mean (SD)	81.974 (30.0322)	-32.813 (16.7847)	127.895 (33.9354)	3.556 (13.4029)	80.441 (34.3643)	-34.532 (11.7910)
	95% CI of Mean	75.016, 88.932	-36.702, -28.923	116.237, 139.553	-1.121, 8.233	65.581, 95.302	-39.631, -29.433

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.23.1 Descriptive Statistics of CYP1A2 Activity (%) PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		31		9	
	Missing, n(%)	0		1(3.1)		0	
	Geometric Mean (CV%)	114.203 (28.3408)		118.520 (29.0306)		140.462 (26.9839)	
	95% CI of Geometric Mean	105.253, 123.914		106.776, 131.555		114.566, 172.211	
	Median	112.330		115.150		135.150	
	Q25, Q75	94.940, 135.240		102.910, 141.110		115.370, 147.870	
	Min, Max	64.55, 231.27		64.59, 196.45		112.78, 260.48	
	Mean (SD)	118.700 (34.6046)		123.146 (34.2740)		145.502 (46.4641)	
	95% CI of Mean	108.539, 128.861		110.574, 135.718		109.786, 181.218	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.23.1 Descriptive Statistics of CYP1A2 Activity (%) PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	31	9	9
	Missing, n(%)	0	0	0	1(3.1)	0	0
	Geometric Mean (CV%)	71.824 (45.9559)		95.139 (43.4021)		85.015 (63.2996)	
	95% CI of Geometric Mean	63.161, 81.675		81.904, 110.512		54.414, 132.825	
	Median	73.010	-37.803	90.440	-18.172	84.370	-32.907
	Q25, Q75	51.780, 99.020	-51.426, -19.110	67.460, 129.885	-34.894, -8.275	61.940, 101.710	-51.439, -25.191
	Min, Max	30.75, 210.87	-78.97, 83.27	44.14, 207.15	-45.78, 29.81	32.71, 267.34	-71.32, 2.63
	Mean (SD)	78.885 (35.8488)	-31.955 (28.7852)	103.370 (43.0415)	-16.706 (19.5223)	99.854 (68.3539)	-35.359 (23.5680)
	95% CI of Mean	68.359, 89.411	-40.407, -23.503	87.851, 118.889	-23.868, -9.545	47.312, 152.396	-53.476, -17.243

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.23.1.1 Descriptive Statistics of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	68		33		23	
	Missing, n(%)	7(9.3)		2(5.7)		1(4.2)	
	Geometric Mean (CV%)	120.582 (30.8880)		119.732 (30.7405)		114.031 (39.5995)	
	95% CI of Geometric Mean	112.085, 129.723		107.630, 133.194		96.682, 134.494	
	Median	118.135		120.600		119.520	
	Q25, Q75	96.885, 146.565		105.140, 141.110		104.550, 146.600	
	Min, Max	64.55, 237.58		61.58, 196.45		43.37, 260.48	
	Mean (SD)	126.159 (39.0481)		124.894 (36.0528)		121.655 (43.8439)	
	95% CI of Mean	116.707, 135.611		112.109, 137.678		102.695, 140.615	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.23.1.1 Descriptive Statistics of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	68	68	34	33	23	23
	Missing, n(%)	7(9.3)	7(9.3)	1(2.9)	2(5.7)	1(4.2)	1(4.2)
	Geometric Mean (CV%)	79.136 (38.1386)		121.768 (26.2686)		73.436 (47.9527)	
	95% CI of Geometric Mean	72.382, 86.519		111.273, 133.254		60.321, 89.403	
	Median	80.925	-33.716	120.535	3.331	74.290	-35.519
	Q25, Q75	62.625, 95.960	-43.020, -26.320	108.430, 149.060	-7.111, 10.482	54.390, 100.020	-47.977, -21.854
	Min, Max	27.39, 175.20	-69.22, 24.98	70.24, 195.23	-17.97, 39.24	21.37, 181.73	-54.92, -19.38
	Mean (SD)	84.348 (30.0090)	-32.352 (17.0999)	125.693 (31.8060)	3.664 (13.5958)	80.441 (34.3643)	-34.532 (11.7910)
	95% CI of Mean	77.084, 91.612	-36.491, -28.212	114.595, 136.791	-1.158, 8.485	65.581, 95.302	-39.631, -29.433

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.23.1.1 Descriptive Statistics of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	45		31		9	
	Missing, n(%)	2(4.3)		1(3.1)		0	
	Geometric Mean (CV%)	114.015 (28.4734)		118.520 (29.0306)		140.462 (26.9839)	
	95% CI of Geometric Mean	104.841, 123.992		106.776, 131.555		114.566, 172.211	
	Median	112.330		115.150		135.150	
	Q25, Q75	95.180, 131.340		102.910, 141.110		115.370, 147.870	
	Min, Max	64.55, 231.27		64.59, 196.45		112.78, 260.48	
	Mean (SD)	118.548 (34.8132)		123.146 (34.2740)		145.502 (46.4641)	
	95% CI of Mean	108.089, 129.008		110.574, 135.718		109.786, 181.218	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.23.1.1 Descriptive Statistics of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	45	45	32	31	9	9
	Missing, n(%)	2(4.3)	2(4.3)	0	1(3.1)	0	0
	Geometric Mean (CV%)	73.233 (45.0581)		95.139 (43.4021)		85.015 (63.2996)	
	95% CI of Geometric Mean	64.359, 83.331		81.904, 110.512		54.414, 132.825	
	Median	73.910	-37.803	90.440	-18.172	84.370	-32.907
	Q25, Q75	52.170, 99.020	-50.622, -19.110	67.460, 129.885	-34.894, -8.275	61.940, 101.710	-51.439, -25.191
	Min, Max	30.75, 210.87	-65.45, 83.27	44.14, 207.15	-45.78, 29.81	32.71, 267.34	-71.32, 2.63
	Mean (SD)	80.182 (35.8979)	-31.018 (28.5410)	103.370 (43.0415)	-16.706 (19.5223)	99.854 (68.3539)	-35.359 (23.5680)
	95% CI of Mean	69.397, 90.967	-39.593, -22.442	87.851, 118.889	-23.868, -9.545	47.312, 152.396	-53.476, -17.243

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.23.2 Descriptive Statistics of CYP1A2 Activity (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	%Change(*)	Value	%Change(*)	Value	%Change(*)
Baseline	n	78		40		38	
	Missing, n (%)	2 (2.5)		1 (2.4)		1 (2.6)	
	Geometric Mean (CV%)	118.646 (32.6279)		123.012 (31.3327)		121.618 (36.3898)	
	95% CI of Geometric Mean	110.435, 127.467		111.543, 135.661		108.307, 136.565	
	Median	118.135		125.915		133.290	
	Q25, Q75	95.180, 143.380		105.325, 153.550		112.780, 147.870	
	Min, Max	55.68, 237.58		61.58, 202.77		43.37, 260.48	
	Mean (SD)	124.661 (39.8317)		128.505 (37.3098)		128.468 (40.6765)	
	95% CI of Mean	115.679, 133.642		116.572, 140.437		115.097, 141.838	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.23.2 Descriptive Statistics of CYP1A2 Activity (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	%Change(*)	Value	%Change(*)	Value	%Change(*)
Day 5	n	78	78	41	40	38	38
	Missing, n (%)	2 (2.5)	2 (2.5)	0	1 (2.4)	1 (2.6)	1 (2.6)
	Geometric Mean (CV%)	76.699 (39.3883)		124.740 (28.2314)		84.251 (45.3039)	
	95% CI of Geometric Mean	70.404, 83.556		114.300, 136.135		73.096, 97.108	
	Median	79.515	-33.716	124.270	3.281	91.505	-30.247
	Q25, Q75	60.870, 95.940	-44.317, -26.490	111.450, 150.920	-7.315, 9.990	65.740, 103.800	-39.611, -20.259
	Min, Max	27.39, 175.20	-69.22, 24.98	68.14, 202.77	-17.97, 39.24	21.37, 191.76	-54.92, 0.00
	Mean (SD)	82.099 (30.1197)	-33.282 (16.9599)	129.318 (34.2556)	3.163 (12.9975)	91.480 (36.1068)	-29.081 (15.5895)
	95% CI of Mean	75.308, 88.890	-37.106, -29.457	118.505, 140.131	-0.994, 7.321	79.612, 103.349	-34.206, -23.957

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.23.2 Descriptive Statistics of CYP1A2 Activity (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	%Change(*)	Value	%Change(*)	Value	%Change(*)
Day 90	n	78	78	41	40	38	38
	Missing, n (%)	2 (2.5)	2 (2.5)	0	1 (2.4)	1 (2.6)	1 (2.6)
	Geometric Mean (CV%)	74.602 (52.5188)		102.656 (44.0457)		93.656 (41.7237)	
	95% CI of Geometric Mean	66.745, 83.384		89.880, 117.249		82.100, 106.837	
	Median	76.860	-35.355	105.370	-13.704	98.430	-23.767
	Q25, Q75	56.940, 108.620	-48.992, -18.843	70.830, 149.890	-26.944, -0.221	70.120, 120.400	-32.541, 0.000
	Min, Max	12.64, 210.87	-88.36, 83.27	44.14, 207.15	-45.78, 29.81	32.71, 267.34	-71.32, 30.60
	Mean (SD)	83.159 (37.3410)	-31.682 (27.3110)	111.612 (45.2583)	-13.525 (19.6214)	101.296 (43.0895)	-19.163 (23.7119)
	95% CI of Mean	74.739, 91.578	-37.840, -25.524	97.326, 125.898	-19.801, -7.250	87.132, 115.459	-26.957, -11.369

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.23.2.1 Descriptive Statistics of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	%Change(*)	Value	%Change(*)	Value	%Change(*)
Baseline	n	72		39		35	
	Missing, n (%)	8 (10.0)		2 (4.9)		4 (10.3)	
	Geometric Mean (CV%)	121.580 (30.7608)		121.446 (30.5756)		122.611 (35.7915)	
	95% CI of Geometric Mean	113.285, 130.482		110.229, 133.805		108.826, 138.142	
	Median	119.055		124.180		133.210	
	Q25, Q75	98.475, 146.565		105.140, 151.950		112.780, 147.870	
	Min, Max	64.55, 237.58		61.58, 196.45		43.37, 260.48	
	Mean (SD)	127.164 (39.2216)		126.600 (35.7741)		129.306 (40.6710)	
	95% CI of Mean	117.947, 136.381		115.003, 138.197		115.335, 143.277	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.23.2.1 Descriptive Statistics of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	%Change(*)	Value	%Change(*)	Value	%Change(*)
Day 5	n	72	72	40	39	35	35
	Missing, n (%)	8 (10.0)	8 (10.0)	1 (2.4)	2 (4.9)	4 (10.3)	4 (10.3)
	Geometric Mean (CV%)	78.998 (38.8902)		123.234 (27.4109)		83.290 (45.0230)	
	95% CI of Geometric Mean	72.329, 86.282		113.070, 134.313		71.862, 96.536	
	Median	80.925	-33.716	124.060	3.331	90.710	-31.643
	Q25, Q75	62.625, 98.220	-43.890, -26.320	109.940, 150.795	-7.519, 10.482	65.740, 103.000	-40.521, -20.293
	Min, Max	27.39, 175.20	-69.22, 24.98	68.14, 195.23	-17.97, 39.24	21.37, 191.76	-54.92, 0.00
	Mean (SD)	84.352 (30.1000)	-32.885 (17.2816)	127.482 (32.5843)	3.244 (13.1572)	90.332 (35.6704)	-30.504 (15.2006)
	95% CI of Mean	77.278, 91.425	-36.947, -28.824	117.060, 137.903	-1.021, 7.510	78.078, 102.585	-35.726, -25.282

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.23.2.1 Descriptive Statistics of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	%Change(*)	Value	%Change(*)	Value	%Change(*)
Day 90	n	72	72	40	39	35	35
	Missing, n (%)	8 (10.0)	8 (10.0)	1 (2.4)	2 (4.9)	4 (10.3)	4 (10.3)
	Geometric Mean (CV%)	76.883 (52.4513)		100.924 (43.0030)		95.292 (40.6970)	
	95% CI of Geometric Mean	68.473, 86.327		88.467, 115.136		83.301, 109.009	
	Median	78.395	-35.355	104.970	-15.581	98.640	-25.191
	Q25, Q75	58.410, 111.470	-47.753, -18.264	70.535, 147.745	-28.357, -0.441	75.130, 120.400	-32.541, 0.000
	Min, Max	12.64, 210.87	-88.36, 83.27	44.14, 207.15	-45.78, 29.81	32.71, 267.34	-71.32, 30.60
	Mean (SD)	85.534 (37.6347)	-31.559 (26.9905)	109.333 (43.3871)	-13.872 (19.7533)	102.692 (42.9981)	-18.572 (23.5343)
	95% CI of Mean	76.690, 94.378	-37.902, -25.216	95.457, 123.210	-20.276, -7.469	87.921, 117.463	-26.657, -10.488

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.24.1 Analysis of CYP1A2 Activity (%) - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CYP1A2 Activity (%)						
Day 5	n	74	33	23		
	Geometric LS Mean (CV%)	75.784	119.300	74.635	63.52 (20.74)	101.54 (20.74)
	95% CI	72.233, 79.508	111.080, 128.127	68.535, 81.278	58.34, 69.17	92.14, 111.89
	p-value (one-sided)				<0.001	
Day 90	n	47	30	9		
	Geometric LS Mean (CV%)	74.308	94.574	70.539	78.57 (36.81)	105.34 (36.81)
	95% CI	66.764, 82.705	82.965, 107.808	55.198, 90.143	66.36, 93.02	80.49, 137.86
	p-value (one-sided)				0.003	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant.

Appendix: 15.3.4.1

Study ID: ZRHM-REXA-08-US

Program: t_anl_cyp.sas

Status: Final

21SEP15

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**Table 15.2.4.24.1.1 Analysis of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CYP1A2 Activity (%)						
Day 5	n	68	33	23		
	Geometric LS Mean (CV%)	77.320	120.986	75.715	63.91 (20.97)	102.12 (20.97)
	95% CI	73.465, 81.377	112.557, 130.045	69.450, 82.546	58.56, 69.74	92.46, 112.79
	p-value (one-sided)				<0.001	
Day 90	n	45	30	9		
	Geometric LS Mean (CV%)	76.286	94.898	70.461	80.39 (34.87)	108.27 (34.87)
	95% CI	68.716, 84.689	83.783, 107.486	55.795, 88.980	68.38, 94.50	83.78, 139.91
	p-value (one-sided)				0.004	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant.

**Table 15.2.4.24.2 Analysis of CYP1A2 Activity (%) - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CYP1A2 Activity (%)						
Day 5	n	78	39	33		
	Geometric LS Mean (CV%)	76.658	121.657	77.904	63.01 (20.78)	98.40 (20.78)
	95% CI	73.169, 80.314	113.941, 129.896	72.556, 83.646	58.18, 68.25	90.43, 107.07
	p-value (one-sided)				<0.001	
Day 90	n	73	34	31		
	Geometric LS Mean (CV%)	74.211	96.315	88.114	77.05 (39.16)	84.22 (39.16)
	95% CI	67.935, 81.067	84.648, 109.590	77.016, 100.810	65.96, 90.01	71.75, 98.86
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant.

Appendix: 15.3.4.1

Study ID: ZRHM-REXA-08-US

Program: t_anl_cyp.sas

Status: Final

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**Table 15.2.4.24.2.1 Analysis of CYP1A2 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CYP1A2 Activity (%)						
Day 5	n	72	39	31		
	Geometric LS Mean (CV%)	78.218	123.487	78.034	63.34 (20.95)	100.24 (20.95)
	95% CI	74.452, 82.173	115.583, 131.931	72.463, 84.033	58.38, 68.72	91.78, 109.47
	p-value (one-sided)				<0.001	
Day 90	n	68	34	29		
	Geometric LS Mean (CV%)	76.030	98.052	91.434	77.54 (38.07)	83.15 (38.07)
	95% CI	69.505, 83.167	86.456, 111.204	79.832, 104.723	66.53, 90.36	70.75, 97.73
	p-value (one-sided)				<0.001	

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Systolic Blood Pressure (mmHg)						
Day 6/Discharge Confinement	n	75	35	24		
	LS Mean	116.1	118.2	115.6	-2.2	0.5
	95% CI	114.1, 118.0	115.4, 121.0	112.2, 119.0	-5.5, 1.2	-3.4, 4.3
Day 30	n	40	34	13		
	LS Mean	117.3	116.8	116.9	0.5	0.4
	95% CI	114.4, 120.1	113.7, 119.9	112.0, 121.9	-3.6, 4.6	-5.3, 6.1
Day 60	n	39	35	12		
	LS Mean	117.0	115.9	115.8	1.1	1.1
	95% CI	113.8, 120.2	112.5, 119.2	109.9, 121.7	-3.5, 5.7	-5.5, 7.8

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Systolic Blood Pressure (mmHg)						
Day 91/Discharge Ambulatory	n	47	32	9		
	LS Mean	116.5	117.2	114.8	-0.7	1.7
	95% CI	114.0, 118.9	114.2, 120.1	109.2, 120.4	-4.5, 3.1	-4.3, 7.7

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Diastolic Blood Pressure (mmHg)						
Day 6/Discharge Confinement	n	75	35	24		
	LS Mean	69.7	72.0	69.5	-2.2	0.2
	95% CI	68.3, 71.2	69.8, 74.1	66.9, 72.1	-4.8, 0.4	-2.7, 3.2
Day 30	n	40	34	13		
	LS Mean	70.5	70.8	68.0	-0.3	2.5
	95% CI	67.9, 73.1	68.0, 73.7	63.5, 72.5	-4.1, 3.4	-2.6, 7.6
Day 60	n	39	35	12		
	LS Mean	70.1	68.9	69.7	1.2	0.4
	95% CI	67.1, 73.1	65.8, 72.1	64.3, 75.1	-3.2, 5.5	-5.7, 6.6

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Diastolic Blood Pressure (mmHg)						
Day 91/Discharge Ambulatory	n	47	32	9		
	LS Mean	70.4	70.2	68.0	0.2	2.4
	95% CI	67.9, 72.9	67.2, 73.2	62.4, 73.6	-3.7, 4.0	-3.7, 8.4

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Weight (kg)						
Day 91/Discharge Ambulatory	n	47	32	9		
	LS Mean	78.06	78.18	78.65	-0.12	-0.59
	95% CI	77.27, 78.85	77.23, 79.13	76.79, 80.51	-1.35, 1.12	-2.60, 1.42

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Waist Circumference (cm)						
Day 91/Discharge Ambulatory	n	47	32	9		
	LS Mean	95.4	97.5	86.1	-2.1	9.3
	95% CI	90.2, 100.7	91.2, 103.9	74.0, 98.2	-10.2, 6.1	-3.8, 22.5

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Triglycerides (mg/dL)						
Day 30	n	40	34	13		
	LS Mean	142.4	141.4	165.5	1.0	-23.1
	95% CI	126.1, 158.7	123.9, 158.9	137.3, 193.7	-22.8, 24.8	-55.7, 9.4
Day 60	n	39	35	12		
	LS Mean	139.4	152.4	148.9	-13.0	-9.5
	95% CI	127.2, 151.6	139.7, 165.2	126.9, 170.8	-30.7, 4.6	-34.6, 15.7
Day 91/Discharge Ambulatory	n	47	32	9		
	LS Mean	136.0	135.1	124.4	0.9	11.6
	95% CI	127.3, 144.7	124.6, 145.6	104.4, 144.3	-12.8, 14.6	-10.1, 33.4

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Cholesterol (mg/dL)						
Day 30	n	40	34	13		
	LS Mean	185.2	186.8	191.7	-1.7	-6.6
	95% CI	178.5, 191.8	179.6, 194.1	180.2, 203.3	-11.4, 8.0	-19.9, 6.7
Day 60	n	39	35	12		
	LS Mean	182.0	185.6	190.1	-3.6	-8.1
	95% CI	175.3, 188.8	178.6, 192.6	178.0, 202.2	-13.3, 6.1	-21.9, 5.7
Day 91/Discharge Ambulatory	n	47	32	9		
	LS Mean	186.3	190.3	187.7	-4.0	-1.4
	95% CI	180.3, 192.2	183.2, 197.5	174.1, 201.2	-13.3, 5.2	-16.1, 13.2

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Hemoglobin A1C (%)						
Day 90	n	47	32	9		
	LS Mean	5.43	5.47	5.30	-0.04	0.14
	95% CI	5.36, 5.51	5.38, 5.56	5.12, 5.47	-0.16, 0.09	-0.05, 0.32

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
HDL Cholesterol (mg/dL)						
Day 30	n	40	34	13		
	LS Mean	50.8	51.7	50.1	-0.9	0.7
	95% CI	48.2, 53.5	48.9, 54.6	45.6, 54.6	-4.8, 2.9	-4.4, 5.9
Day 60	n	39	35	12		
	LS Mean	51.6	50.8	52.0	0.8	-0.5
	95% CI	49.4, 53.7	48.5, 53.1	48.2, 55.8	-2.4, 3.9	-4.8, 3.9
Day 90	n	47	32	9		
	LS Mean	54.7	53.3	53.3	1.4	1.3
	95% CI	52.3, 57.0	50.5, 56.1	48.1, 58.6	-2.3, 5.0	-4.4, 7.1

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
LDL Cholesterol (mg/dL)						
Day 30	n	40	34	13		
	LS Mean	110.8	113.0	116.1	-2.2	-5.3
	95% CI	105.6, 115.9	107.4, 118.5	107.2, 125.0	-9.7, 5.3	-15.5, 4.8
Day 60	n	39	35	12		
	LS Mean	108.6	110.7	117.2	-2.1	-8.6
	95% CI	103.4, 113.9	105.2, 116.2	107.7, 126.6	-9.7, 5.5	-19.3, 2.2
Day 90	n	47	32	9		
	LS Mean	111.0	114.3	116.1	-3.3	-5.1
	95% CI	105.4, 116.6	107.6, 121.0	103.5, 128.8	-12.0, 5.4	-18.9, 8.6

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Apolipoprotein A1 (mg/dL)						
Day 90	n	47	32	9		
	LS Mean	151.5	148.5	147.8	3.1	3.7
	95% CI	146.6, 156.4	142.5, 154.4	136.7, 158.9	-4.6, 10.7	-8.3, 15.7

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.3.2

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**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Apolipoprotein B (mg/dL)						
Day 90	n	47	32	9		
	LS Mean	85.00	86.61	88.18	-1.60	-3.17
	95% CI	81.39, 88.62	82.26, 90.95	79.89, 96.46	-7.24, 4.03	-12.14, 5.79

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.3.2

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**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Leukocytes (GI/L)						
Day 6/Discharge Confinement	n	75	35	24		
	LS Mean	7.64	8.11	7.10	-0.47	0.54
	95% CI	7.36, 7.92	7.70, 8.51	6.61, 7.58	-0.96, 0.02	-0.02, 1.09
Day 30	n	40	34	13		
	LS Mean	7.26	7.58	6.90	-0.32	0.36
	95% CI	6.83, 7.70	7.11, 8.05	6.14, 7.66	-0.95, 0.31	-0.51, 1.24
Day 60	n	39	35	12		
	LS Mean	7.39	7.43	6.86	-0.04	0.53
	95% CI	6.99, 7.79	7.01, 7.85	6.12, 7.60	-0.62, 0.54	-0.31, 1.37

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Leukocytes (GI/L)						
Day 91/Discharge Ambulatory	n	47	32	9		
	LS Mean	7.26	7.09	6.15	0.17	1.11
	95% CI	6.84, 7.68	6.59, 7.59	5.19, 7.11	-0.47, 0.81	0.07, 2.15

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.6.7

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**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Neutrophils (GI/L)						
Day 6/Discharge Confinement	n	75	35	24		
	LS Mean	4.29	4.60	3.83	-0.31	0.47
	95% CI	4.07, 4.51	4.27, 4.92	3.44, 4.21	-0.69, 0.08	0.03, 0.91
Day 30	n	40	34	13		
	LS Mean	4.01	4.29	3.55	-0.28	0.46
	95% CI	3.65, 4.38	3.90, 4.69	2.91, 4.19	-0.81, 0.25	-0.27, 1.19
Day 60	n	39	35	12		
	LS Mean	4.13	4.19	3.52	-0.06	0.61
	95% CI	3.83, 4.44	3.88, 4.51	2.97, 4.08	-0.49, 0.37	-0.02, 1.24

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Neutrophils (GI/L)						
Day 91/Discharge Ambulatory	n	47	32	9		
	LS Mean	4.46	4.44	3.46	0.02	1.00
	95% CI	4.12, 4.80	4.03, 4.85	2.68, 4.24	-0.51, 0.55	0.15, 1.85

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Lymphocytes (GI/L)						
Day 6/Discharge Confinement	n	75	35	24		
	LS Mean	2.66	2.81	2.61	-0.15	0.05
	95% CI	2.56, 2.76	2.66, 2.95	2.43, 2.78	-0.32, 0.03	-0.15, 0.25
Day 30	n	40	34	13		
	LS Mean	2.58	2.60	2.68	-0.02	-0.10
	95% CI	2.41, 2.75	2.41, 2.78	2.38, 2.98	-0.27, 0.23	-0.44, 0.24
Day 60	n	39	35	12		
	LS Mean	2.61	2.61	2.68	0.00	-0.07
	95% CI	2.45, 2.77	2.44, 2.78	2.39, 2.96	-0.23, 0.22	-0.39, 0.25

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Lymphocytes (GI/L)						
Day 91/Discharge Ambulatory	n	47	32	9		
	LS Mean	2.19	2.05	2.07	0.14	0.12
	95% CI	2.07, 2.32	1.90, 2.21	1.79, 2.36	-0.06, 0.34	-0.19, 0.43

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Monocytes (GI/L)						
Day 6/Discharge Confinement	n	75	35	24		
	LS Mean	0.45	0.45	0.43	0.00	0.02
	95% CI	0.42, 0.48	0.41, 0.49	0.39, 0.48	-0.05, 0.04	-0.04, 0.07
Day 30	n	40	34	13		
	LS Mean	0.44	0.44	0.39	0.00	0.05
	95% CI	0.41, 0.48	0.40, 0.48	0.33, 0.46	-0.05, 0.05	-0.02, 0.12
Day 60	n	39	35	12		
	LS Mean	0.45	0.40	0.35	0.05	0.10
	95% CI	0.40, 0.50	0.35, 0.46	0.27, 0.43	-0.02, 0.11	0.00, 0.20

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Monocytes (GI/L)						
Day 91/Discharge Ambulatory	n	47	32	9		
	LS Mean	0.44	0.41	0.36	0.03	0.08
	95% CI	0.39, 0.49	0.35, 0.47	0.25, 0.47	-0.05, 0.10	-0.04, 0.20

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Eosinophils (GI/L)						
Day 6/Discharge Confinement	n	75	35	24		
	LS Mean	0.19	0.22	0.18	-0.03	0.01
	95% CI	0.17, 0.21	0.19, 0.25	0.15, 0.21	-0.06, 0.00	-0.03, 0.05
Day 30	n	40	34	13		
	LS Mean	0.19	0.21	0.20	-0.01	-0.01
	95% CI	0.16, 0.22	0.18, 0.24	0.16, 0.25	-0.05, 0.03	-0.06, 0.04
Day 60	n	39	35	12		
	LS Mean	0.17	0.19	0.18	-0.02	-0.02
	95% CI	0.14, 0.20	0.16, 0.22	0.13, 0.23	-0.06, 0.02	-0.07, 0.04

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Eosinophils (GI/L)						
Day 91/Discharge Ambulatory	n	47	32	9		
	LS Mean	0.15	0.16	0.12	-0.01	0.03
	95% CI	0.12, 0.17	0.13, 0.18	0.07, 0.17	-0.04, 0.03	-0.02, 0.08

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.6.7

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**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Basophils (GI/L)						
Day 6/Discharge Confinement	n	75	35	24		
	LS Mean	0.05	0.05	0.04	-0.01	0.00
	95% CI	0.04, 0.05	0.04, 0.06	0.03, 0.05	-0.02, 0.00	-0.01, 0.02
Day 30	n	40	34	13		
	LS Mean	0.04	0.05	0.04	-0.01	0.00
	95% CI	0.03, 0.06	0.04, 0.06	0.02, 0.06	-0.02, 0.01	-0.01, 0.02
Day 60	n	39	35	12		
	LS Mean	0.05	0.04	0.04	0.01	0.01
	95% CI	0.04, 0.07	0.03, 0.06	0.02, 0.06	-0.01, 0.03	-0.01, 0.04

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Basophils (GI/L)						
Day 91/Discharge Ambulatory	n	47	32	9		
	LS Mean	0.04	0.05	0.03	0.00	0.01
	95% CI	0.03, 0.06	0.04, 0.06	0.01, 0.05	-0.02, 0.01	-0.01, 0.03

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.6.7

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**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Glucose (mg/dL)						
Day 30	n	40	34	13		
	Geometric LS Mean (CV%)	94.1	92.8	92.9	101.39 (5.80)	101.33 (5.80)
	95% CI	92.4, 95.9	91.0, 94.8	89.9, 96.0	98.69, 104.17	97.65, 105.14
Day 60	n	39	35	12		
	Geometric LS Mean (CV%)	93.9	92.1	98.8	101.93 (8.84)	95.09 (8.84)
	95% CI	91.2, 96.7	89.4, 95.0	93.7, 104.1	97.80, 106.24	89.58, 100.93
Day 91/Discharge Ambulatory	n	47	32	9		
	Geometric LS Mean (CV%)	94.2	92.5	96.6	101.79 (8.16)	97.54 (8.16)
	95% CI	91.9, 96.5	89.8, 95.3	91.3, 102.1	98.03, 105.69	91.89, 103.54

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
C Reactive Protein (mg/L)						
Day 30	n	40	34	13		
	Geometric LS Mean (CV%)	1.29	1.71	0.91	75.46 (81.23)	141.22 (81.23)
	95% CI	1.02, 1.63	1.33, 2.19	0.61, 1.36	54.06, 105.32	89.77, 222.16
Day 60	n	39	35	12		
	Geometric LS Mean (CV%)	1.25	1.40	1.34	89.48 (89.73)	93.06 (89.73)
	95% CI	0.97, 1.61	1.07, 1.82	0.85, 2.11	62.18, 128.75	55.70, 155.48
Day 90	n	47	32	9		
	Geometric LS Mean (CV%)	1.23	1.46	1.26	83.77 (95.80)	97.39 (95.80)
	95% CI	0.96, 1.56	1.09, 1.95	0.72, 2.18	57.67, 121.69	53.83, 176.19

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Homocysteine (umol/L)						
Day 30	n	40	34	13		
	Geometric LS Mean (CV%)	10.05	9.66	10.58	104.02 (16.55)	95.01 (16.55)
	95% CI	9.53, 10.60	9.13, 10.23	9.65, 11.60	96.34, 112.32	85.54, 105.51
Day 60	n	39	35	12		
	Geometric LS Mean (CV%)	10.23	9.96	9.66	102.71 (18.64)	105.96 (18.64)
	95% CI	9.63, 10.87	9.35, 10.61	8.65, 10.77	94.18, 112.01	93.56, 120.00
Day 90	n	47	32	9		
	Geometric LS Mean (CV%)	10.83	10.64	10.14	101.84 (20.12)	106.86 (20.12)
	95% CI	10.21, 11.50	9.90, 11.42	8.86, 11.61	92.90, 111.64	92.33, 123.66

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Fibrinogen (mg/dL)						
Day 30	n	40	34	11		
	Geometric LS Mean (CV%)	303.2	315.0	295.5	96.26 (15.39)	102.60 (15.39)
	95% CI	288.6, 318.5	298.6, 332.2	269.4, 324.1	89.62, 103.39	92.44, 113.87
Day 60	n	39	35	12		
	Geometric LS Mean (CV%)	305.4	298.7	307.8	102.22 (16.06)	99.22 (16.06)
	95% CI	289.8, 321.8	282.8, 315.5	280.2, 338.0	94.85, 110.17	89.18, 110.39
Day 90	n	47	32	9		
	Geometric LS Mean (CV%)	305.0	310.1	316.0	98.37 (17.19)	96.52 (17.19)
	95% CI	289.9, 320.9	291.7, 329.6	281.6, 354.6	90.92, 106.42	85.18, 109.38

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Intercellular Adhesion Molecule 1 (ng/mL)						
Day 6/Discharge Confinement	n	73	35	24		
	Geometric LS Mean (CV%)	228.20	245.53	227.24	92.94 (14.48)	100.43 (14.48)
	95% CI	220.58, 236.10	233.92, 257.72	214.32, 240.94	87.64, 98.56	93.90, 107.40
Day 30	n	39	34	13		
	Geometric LS Mean (CV%)	226.98	245.26	225.43	92.55 (15.83)	100.69 (15.83)
	95% CI	215.69, 238.86	232.28, 258.96	206.57, 246.01	85.95, 99.65	91.03, 111.37
Day 60	n	37	35	12		
	Geometric LS Mean (CV%)	226.60	248.98	227.80	91.01 (19.71)	99.48 (19.71)
	95% CI	212.18, 242.00	232.97, 266.08	203.00, 255.62	82.90, 99.92	87.11, 113.59

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Intercellular Adhesion Molecule 1 (ng/mL)						
Day 90	n	45	32	9		
	Geometric LS Mean (CV%)	229.84	257.07	231.60	89.41 (15.24)	99.24 (15.24)
	95% CI	219.48, 240.68	243.58, 271.30	208.89, 256.79	83.29, 95.97	88.65, 111.09

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Platelets (GI/L)						
Day 6/Discharge Confinement	n	75	35	24		
	Geometric LS Mean (CV%)	278.3	268.4	269.8	103.68 (12.09)	103.14 (12.09)
	95% CI	270.5, 286.2	257.7, 279.6	256.9, 283.4	98.72, 108.89	97.53, 109.08
Day 30	n	40	34	13		
	Geometric LS Mean (CV%)	278.1	258.7	266.6	107.51 (13.53)	104.30 (13.53)
	95% CI	266.3, 290.4	246.8, 271.1	247.4, 287.4	100.95, 114.49	95.72, 113.64
Day 60	n	39	35	12		
	Geometric LS Mean (CV%)	259.8	244.4	252.4	106.33 (11.87)	102.94 (11.87)
	95% CI	250.0, 270.1	234.6, 254.5	235.5, 270.6	100.56, 112.43	95.12, 111.40

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Platelets (GI/L)						
Day 91/Discharge Ambulatory	n	47	32	9		
	Geometric LS Mean (CV%)	249.2	240.8	244.0	103.49 (15.58)	102.14 (15.58)
	95% CI	238.0, 261.0	227.8, 254.6	219.6, 271.0	96.28, 111.24	91.14, 114.48

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Prostaglandin F2 Alpha (pg/mg creat)						
Day 5	n	69	34	21		
	Geometric LS Mean (CV%)	229.56	266.34	234.86	86.19 (22.83)	97.75 (22.83)
	95% CI	217.36, 242.45	246.52, 287.75	212.98, 258.98	78.45, 94.70	87.42, 109.29
Day 30	n	39	33	12		
	Geometric LS Mean (CV%)	277.97	311.34	283.18	89.28 (29.72)	98.16 (29.72)
	95% CI	252.66, 305.83	281.03, 344.91	238.68, 335.98	77.64, 102.68	80.67, 119.44
Day 60	n	37	34	11		
	Geometric LS Mean (CV%)	280.22	303.86	272.15	92.22 (29.23)	102.96 (29.23)
	95% CI	254.53, 308.50	275.12, 335.60	228.29, 324.45	80.29, 105.93	84.33, 125.72

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Prostaglandin F2 Alpha (pg/mg creat)						
Day 90	n	45	32	9		
	Geometric LS Mean (CV%)	264.61	305.75	279.73	86.54 (27.01)	94.59 (27.01)
	95% CI	244.14, 286.79	277.98, 336.31	233.63, 334.92	76.39, 98.05	77.74, 115.10

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
11-Dehydro-Thromboxane B2 (pg/mg creat)						
Day 5	n	69	34	21		
	Geometric LS Mean (CV%)	532.40	633.87	504.92	83.99 (26.87)	105.44 (26.87)
	95% CI	499.40, 567.58	579.18, 693.72	450.36, 566.08	75.26, 93.74	92.53, 120.15
Day 30	n	39	33	12		
	Geometric LS Mean (CV%)	420.44	451.49	409.70	93.12 (43.34)	102.62 (43.34)
	95% CI	367.01, 481.65	390.42, 522.11	322.54, 520.41	76.43, 113.46	78.04, 134.94
Day 60	n	37	34	11		
	Geometric LS Mean (CV%)	441.22	429.68	308.55	102.69 (63.29)	143.00 (63.29)
	95% CI	362.75, 536.66	351.67, 524.99	216.51, 439.72	77.57, 135.93	95.54, 214.01

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1 Analysis of Risk Markers - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
11-Dehydro-Thromboxane B2 (pg/mg creat)						
Day 90	n	45	32	9		
	Geometric LS Mean (CV%)	428.66	444.47	412.67	96.44 (56.57)	103.88 (56.57)
	95% CI	365.22, 503.13	368.57, 536.00	288.89, 589.47	75.43, 123.31	70.42, 153.23

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
11-Dehydro-Thromboxane B2 (pg/mg creat)						
Day 5	n	69	34	21		
	Geometric LS Mean (CV%)	532.40	633.87	504.92	83.99 (26.87)	105.44 (26.87)
	95% CI	499.40, 567.58	579.18, 693.72	450.36, 566.08	75.26, 93.74	92.53, 120.15
Day 30	n	39	33	12		
	Geometric LS Mean (CV%)	420.44	451.49	409.70	93.12 (43.34)	102.62 (43.34)
	95% CI	367.01, 481.65	390.42, 522.11	322.54, 520.41	76.43, 113.46	78.04, 134.94

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix: 15.3.3.1

Study ID: ZRHM-REXA-08-US

Program: t_anl_dtx.sas

Status: Final

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**Table 15.2.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
11-Dehydro-Thromboxane B2 (pg/mg creat)						
Day 60	n	37	33	11		
	Geometric LS Mean (CV%)	439.97	425.99	307.80	103.28 (63.73)	142.94 (63.73)
	95% CI	361.22, 535.89	347.33, 522.46	215.51, 439.60	77.71, 137.27	95.27, 214.46
Day 90	n	45	31	9		
	Geometric LS Mean (CV%)	427.56	440.06	411.79	97.16 (56.90)	103.83 (56.90)
	95% CI	363.92, 502.33	363.64, 532.56	287.74, 589.30	75.72, 124.67	70.24, 153.48

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Systolic Blood Pressure (mmHg)						
Day 6/Discharge Confinement	n	79	41	39		
	LS Mean	115.9	117.8	114.6	-1.9	1.2
	95% CI	114.0, 117.7	115.2, 120.3	112.0, 117.3	-4.9, 1.2	-2.0, 4.4
Day 30	n	79	41	39		
	LS Mean	116.7	116.0	114.9	0.6	1.8
	95% CI	114.6, 118.7	113.2, 118.8	111.9, 117.9	-2.8, 4.1	-1.8, 5.4
Day 60	n	79	41	39		
	LS Mean	115.8	114.7	115.3	1.1	0.5
	95% CI	113.7, 118.0	111.8, 117.7	112.2, 118.4	-2.5, 4.7	-3.3, 4.3

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Systolic Blood Pressure (mmHg)						
Day 91/Discharge Ambulatory	n	79	41	39		
	LS Mean	116.5	116.4	117.1	0.1	-0.5
	95% CI	114.5, 118.5	113.8, 119.1	114.2, 119.9	-3.2, 3.3	-4.0, 2.9

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Diastolic Blood Pressure (mmHg)						
Day 6/Discharge Confinement	n	79	41	39		
	LS Mean	69.5	71.6	69.1	-2.1	0.5
	95% CI	68.1, 71.0	69.6, 73.6	67.1, 71.1	-4.5, 0.3	-2.0, 2.9
Day 30	n	79	41	39		
	LS Mean	70.0	70.6	68.5	-0.6	1.5
	95% CI	68.2, 71.8	68.2, 73.1	66.0, 71.0	-3.6, 2.4	-1.5, 4.6
Day 60	n	79	41	39		
	LS Mean	69.7	68.0	69.3	1.7	0.4
	95% CI	67.8, 71.6	65.4, 70.6	66.6, 72.0	-1.5, 4.8	-2.8, 3.6

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Diastolic Blood Pressure (mmHg)						
Day 91/Discharge Ambulatory	n	79	41	39		
	LS Mean	70.3	69.5	71.0	0.9	-0.7
	95% CI	68.5, 72.2	66.9, 72.0	68.4, 73.6	-2.2, 3.9	-3.8, 2.5

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Weight (kg)						
Day 91/Discharge Ambulatory	n	79	41	39		
	LS Mean	77.79	78.24	78.03	-0.45	-0.25
	95% CI	77.18, 78.39	77.40, 79.07	77.17, 78.89	-1.47, 0.58	-1.29, 0.80

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.6.12

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Waist Circumference (cm)						
Day 91/Discharge Ambulatory	n	79	41	39		
	LS Mean	97.4	95.0	94.8	2.4	2.5
	95% CI	92.9, 101.9	88.8, 101.1	88.5, 101.2	-5.1, 10.0	-5.2, 10.3

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Triglycerides (mg/dL)						
Day 30	n	79	41	39		
	LS Mean	136.3	133.2	150.9	3.1	-14.5
	95% CI	125.9, 146.8	118.9, 147.5	136.0, 165.7	-14.5, 20.7	-32.5, 3.4
Day 60	n	79	41	39		
	LS Mean	136.6	147.3	142.7	-10.7	-6.1
	95% CI	127.6, 145.6	134.9, 159.7	129.9, 155.5	-26.0, 4.5	-21.6, 9.4
Day 91/Discharge Ambulatory	n	79	41	39		
	LS Mean	132.0	137.2	138.8	-5.2	-6.8
	95% CI	122.8, 141.2	124.6, 149.9	125.7, 151.9	-20.8, 10.4	-22.7, 9.1

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Cholesterol (mg/dL)						
Day 30	n	79	41	39		
	LS Mean	183.7	185.4	188.8	-1.6	-5.0
	95% CI	178.8, 188.7	178.6, 192.2	181.8, 195.7	-10.0, 6.7	-13.5, 3.5
Day 60	n	79	41	39		
	LS Mean	181.3	184.1	188.9	-2.8	-7.6
	95% CI	176.4, 186.1	177.5, 190.7	182.1, 195.7	-10.9, 5.3	-15.9, 0.7
Day 91/Discharge Ambulatory	n	79	41	39		
	LS Mean	186.5	190.6	193.2	-4.1	-6.7
	95% CI	181.4, 191.6	183.6, 197.6	186.0, 200.4	-12.7, 4.5	-15.4, 2.1

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Hemoglobin A1C (%)						
Day 90	n	79	41	39		
	LS Mean	5.42	5.48	5.43	-0.06	-0.01
	95% CI	5.36, 5.48	5.39, 5.56	5.35, 5.52	-0.16, 0.04	-0.12, 0.09

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
HDL Cholesterol (mg/dL)						
Day 30	n	79	41	39		
	LS Mean	52.8	53.3	51.7	-0.5	1.1
	95% CI	50.7, 54.9	50.4, 56.2	48.7, 54.7	-4.0, 3.0	-2.5, 4.7
Day 60	n	79	41	39		
	LS Mean	53.8	52.3	50.4	1.5	3.3
	95% CI	51.9, 55.7	49.6, 54.9	47.7, 53.2	-1.7, 4.8	0.1, 6.6
Day 90	n	79	41	39		
	LS Mean	56.7	52.7	52.4	4.0	4.3
	95% CI	54.6, 58.9	49.7, 55.6	49.4, 55.5	0.4, 7.7	0.6, 8.0

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
LDL Cholesterol (mg/dL)						
Day 30	n	79	41	39		
	LS Mean	109.4	111.1	112.9	-1.7	-3.5
	95% CI	105.2, 113.6	105.4, 116.8	107.0, 118.8	-8.7, 5.3	-10.7, 3.6
Day 60	n	79	41	39		
	LS Mean	106.2	108.9	116.2	-2.6	-10.0
	95% CI	101.9, 110.6	102.9, 114.8	110.1, 122.4	-10.0, 4.7	-17.5, -2.5
Day 90	n	79	41	39		
	LS Mean	111.0	114.8	118.0	-3.8	-7.0
	95% CI	106.1, 116.0	108.0, 121.6	111.0, 125.0	-12.1, 4.6	-15.5, 1.5

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Apolipoprotein A1 (mg/dL)						
Day 90	n	79	41	39		
	LS Mean	154.3	147.7	142.1	6.6	12.1
	95% CI	150.1, 158.5	141.8, 153.5	136.2, 148.1	-0.5, 13.8	4.9, 19.4

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.3.2

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Apolipoprotein B (mg/dL)						
Day 90	n	79	41	39		
	LS Mean	86.59	87.61	89.49	-1.03	-2.91
	95% CI	83.71, 89.46	83.67, 91.56	85.42, 93.56	-5.88, 3.82	-7.85, 2.03

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.3.2

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Leukocytes (GI/L)						
Day 6/Discharge Confinement	n	79	41	39		
	LS Mean	7.58	8.03	7.24	-0.45	0.34
	95% CI	7.32, 7.84	7.67, 8.39	6.88, 7.61	-0.89, -0.01	-0.11, 0.78
Day 30	n	79	41	39		
	LS Mean	7.15	7.56	7.17	-0.41	-0.02
	95% CI	6.86, 7.44	7.17, 7.96	6.77, 7.58	-0.90, 0.08	-0.52, 0.47
Day 60	n	79	41	39		
	LS Mean	7.06	7.31	6.97	-0.25	0.09
	95% CI	6.78, 7.34	6.92, 7.69	6.58, 7.36	-0.72, 0.22	-0.38, 0.56

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Leukocytes (GI/L)						
Day 91/Discharge Ambulatory	n	79	41	39		
	LS Mean	7.01	7.21	7.29	-0.20	-0.28
	95% CI	6.67, 7.35	6.74, 7.67	6.81, 7.76	-0.77, 0.38	-0.86, 0.30

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.6.7

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Neutrophils (GI/L)						
Day 6/Discharge Confinement	n	79	41	39		
	LS Mean	4.26	4.52	3.98	-0.26	0.28
	95% CI	4.05, 4.47	4.23, 4.80	3.69, 4.27	-0.61, 0.09	-0.07, 0.64
Day 30	n	79	41	39		
	LS Mean	3.94	4.25	3.85	-0.31	0.09
	95% CI	3.69, 4.18	3.91, 4.59	3.50, 4.19	-0.72, 0.10	-0.33, 0.51
Day 60	n	79	41	39		
	LS Mean	3.88	4.08	3.69	-0.20	0.19
	95% CI	3.66, 4.11	3.77, 4.40	3.37, 4.02	-0.58, 0.19	-0.20, 0.58

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Neutrophils (GI/L)						
Day 91/Discharge Ambulatory	n	79	41	39		
	LS Mean	4.19	4.44	4.28	-0.25	-0.08
	95% CI	3.91, 4.48	4.05, 4.84	3.87, 4.68	-0.74, 0.23	-0.58, 0.41

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.6.7

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Lymphocytes (GI/L)						
Day 6/Discharge Confinement	n	79	41	39		
	LS Mean	2.63	2.80	2.58	-0.17	0.05
	95% CI	2.53, 2.73	2.66, 2.93	2.45, 2.72	-0.33, 0.00	-0.11, 0.21
Day 30	n	79	41	39		
	LS Mean	2.55	2.61	2.69	-0.06	-0.14
	95% CI	2.44, 2.66	2.46, 2.76	2.54, 2.84	-0.25, 0.12	-0.33, 0.04
Day 60	n	79	41	39		
	LS Mean	2.52	2.59	2.65	-0.07	-0.13
	95% CI	2.42, 2.63	2.45, 2.74	2.50, 2.80	-0.25, 0.11	-0.31, 0.05

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Lymphocytes (GI/L)						
Day 91/Discharge Ambulatory	n	79	41	39		
	LS Mean	2.19	2.16	2.39	0.03	-0.19
	95% CI	2.08, 2.31	2.01, 2.31	2.23, 2.54	-0.15, 0.22	-0.38, 0.00

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Monocytes (GI/L)						
Day 6/Discharge Confinement	n	79	41	39		
	LS Mean	0.45	0.45	0.44	0.00	0.01
	95% CI	0.42, 0.48	0.41, 0.48	0.40, 0.47	-0.04, 0.04	-0.03, 0.05
Day 30	n	79	41	39		
	LS Mean	0.43	0.43	0.41	-0.01	0.02
	95% CI	0.40, 0.45	0.40, 0.47	0.37, 0.45	-0.05, 0.04	-0.03, 0.06
Day 60	n	79	41	39		
	LS Mean	0.42	0.40	0.40	0.02	0.02
	95% CI	0.39, 0.45	0.35, 0.44	0.35, 0.44	-0.03, 0.08	-0.03, 0.08

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Monocytes (GI/L)						
Day 91/Discharge Ambulatory	n	79	41	39		
	LS Mean	0.41	0.41	0.42	0.00	-0.01
	95% CI	0.37, 0.45	0.36, 0.46	0.37, 0.47	-0.06, 0.06	-0.07, 0.05

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Eosinophils (GI/L)						
Day 6/Discharge Confinement	n	79	41	39		
	LS Mean	0.19	0.22	0.20	-0.03	0.00
	95% CI	0.17, 0.21	0.20, 0.25	0.17, 0.22	-0.06, 0.00	-0.03, 0.03
Day 30	n	79	41	39		
	LS Mean	0.19	0.22	0.19	-0.02	0.01
	95% CI	0.17, 0.22	0.19, 0.25	0.16, 0.21	-0.06, 0.01	-0.02, 0.04
Day 60	n	79	41	39		
	LS Mean	0.18	0.20	0.18	-0.02	0.00
	95% CI	0.16, 0.20	0.17, 0.23	0.15, 0.21	-0.05, 0.02	-0.03, 0.03

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Eosinophils (GI/L)						
Day 91/Discharge Ambulatory	n	79	41	39		
	LS Mean	0.16	0.18	0.16	-0.03	-0.01
	95% CI	0.14, 0.18	0.16, 0.21	0.13, 0.19	-0.06, 0.01	-0.04, 0.03

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Basophils (GI/L)						
Day 6/Discharge Confinement	n	79	41	39		
	LS Mean	0.04	0.05	0.05	-0.01	0.00
	95% CI	0.04, 0.05	0.04, 0.06	0.04, 0.06	-0.02, 0.01	-0.02, 0.01
Day 30	n	79	41	39		
	LS Mean	0.05	0.05	0.04	-0.01	0.00
	95% CI	0.04, 0.06	0.04, 0.06	0.03, 0.05	-0.02, 0.01	-0.01, 0.02
Day 60	n	79	41	39		
	LS Mean	0.05	0.05	0.04	0.00	0.00
	95% CI	0.04, 0.06	0.03, 0.06	0.03, 0.06	-0.01, 0.02	-0.01, 0.02

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Basophils (GI/L)						
Day 91/Discharge Ambulatory	n	79	41	39		
	LS Mean	0.04	0.05	0.04	-0.01	0.00
	95% CI	0.03, 0.05	0.04, 0.06	0.03, 0.05	-0.02, 0.00	-0.01, 0.01

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Glucose (mg/dL)						
Day 30	n	79	41	39		
	Geometric LS Mean (CV%)	93.5	92.3	93.5	101.33 (5.76)	99.99 (5.76)
	95% CI	92.2, 94.8	90.6, 94.0	91.8, 95.3	99.13, 103.57	97.77, 102.25
Day 60	n	79	41	39		
	Geometric LS Mean (CV%)	93.1	91.3	95.8	101.93 (7.77)	97.23 (7.77)
	95% CI	91.4, 94.8	89.1, 93.6	93.4, 98.2	98.96, 104.99	94.34, 100.20
Day 91/Discharge Ambulatory	n	79	41	39		
	Geometric LS Mean (CV%)	93.5	91.8	95.8	101.89 (7.89)	97.63 (7.89)
	95% CI	91.9, 95.3	89.5, 94.1	93.4, 98.3	98.88, 105.00	94.69, 100.67

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
C Reactive Protein (mg/L)						
Day 30	n	79	41	39		
	Geometric LS Mean (CV%)	1.31	1.61	1.03	81.02 (89.36)	127.11 (89.36)
	95% CI	1.10, 1.56	1.27, 2.05	0.80, 1.32	60.50, 108.48	94.44, 171.08
Day 60	n	79	41	39		
	Geometric LS Mean (CV%)	1.39	1.37	1.23	101.60 (113.77)	113.11 (113.77)
	95% CI	1.13, 1.72	1.03, 1.82	0.92, 1.65	71.80, 143.78	79.44, 161.04
Day 90	n	79	41	39		
	Geometric LS Mean (CV%)	1.36	1.58	1.35	86.44 (104.43)	101.14 (104.43)
	95% CI	1.12, 1.66	1.20, 2.06	1.02, 1.78	62.32, 119.90	72.50, 141.09

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Homocysteine (umol/L)						
Day 30	n	79	41	39		
	Geometric LS Mean (CV%)	9.48	9.35	9.84	101.36 (16.44)	96.37 (16.44)
	95% CI	9.13, 9.84	8.89, 9.84	9.33, 10.37	95.25, 107.86	90.45, 102.67
Day 60	n	79	41	39		
	Geometric LS Mean (CV%)	9.83	9.48	9.62	103.67 (17.27)	102.20 (17.27)
	95% CI	9.45, 10.22	8.99, 10.01	9.10, 10.17	97.12, 110.66	95.63, 109.22
Day 90	n	79	41	39		
	Geometric LS Mean (CV%)	10.30	10.16	10.22	101.33 (18.95)	100.75 (18.95)
	95% CI	9.86, 10.74	9.58, 10.77	9.62, 10.85	94.34, 108.84	93.68, 108.36

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Fibrinogen (mg/dL)						
Day 30	n	76	41	36		
	Geometric LS Mean (CV%)	303.9	312.8	312.2	97.16 (15.51)	97.33 (15.51)
	95% CI	293.3, 314.8	298.1, 328.1	296.6, 328.7	91.59, 103.07	91.50, 103.53
Day 60	n	76	41	36		
	Geometric LS Mean (CV%)	300.7	299.1	313.0	100.54 (16.16)	96.06 (16.16)
	95% CI	289.8, 312.0	284.5, 314.4	296.7, 330.2	94.54, 106.92	90.08, 102.45
Day 90	n	76	41	36		
	Geometric LS Mean (CV%)	304.7	308.4	315.2	98.79 (16.79)	96.67 (16.79)
	95% CI	293.2, 316.6	292.9, 324.8	298.1, 333.2	92.67, 105.30	90.43, 103.35

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Intercellular Adhesion Molecule 1 (ng/mL)						
Day 6/Discharge Confinement	n	77	41	39		
	Geometric LS Mean (CV%)	228.13	242.05	229.90	94.25 (15.50)	99.23 (15.50)
	95% CI	220.25, 236.29	230.76, 253.89	218.83, 241.52	88.86, 99.97	93.43, 105.39
Day 30	n	77	41	39		
	Geometric LS Mean (CV%)	227.72	246.05	230.22	92.55 (16.03)	98.92 (16.03)
	95% CI	219.59, 236.15	234.20, 258.50	218.77, 242.26	87.08, 98.36	92.95, 105.26
Day 60	n	77	41	39		
	Geometric LS Mean (CV%)	224.71	244.33	227.37	91.97 (17.99)	98.83 (17.99)
	95% CI	215.74, 234.05	231.19, 258.23	214.74, 240.74	85.90, 98.46	92.18, 105.97

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Intercellular Adhesion Molecule 1 (ng/mL)						
Day 90	n	77	41	39		
	Geometric LS Mean (CV%)	227.34	246.47	235.25	92.24 (17.85)	96.64 (17.85)
	95% CI	218.34, 236.72	233.31, 260.38	222.29, 248.98	86.20, 98.70	90.18, 103.56

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Platelets (GI/L)						
Day 6/Discharge Confinement	n	79	41	39		
	Geometric LS Mean (CV%)	278.7	273.6	267.8	101.86 (12.13)	104.04 (12.13)
	95% CI	271.1, 286.4	263.4, 284.1	257.7, 278.4	97.27, 106.68	99.27, 109.04
Day 30	n	79	41	39		
	Geometric LS Mean (CV%)	274.8	258.5	264.0	106.30 (13.36)	104.07 (13.36)
	95% CI	266.6, 283.2	248.0, 269.5	253.0, 275.5	101.03, 111.84	98.84, 109.59
Day 60	n	79	41	39		
	Geometric LS Mean (CV%)	257.5	245.6	254.0	104.83 (12.90)	101.39 (12.90)
	95% CI	250.1, 265.1	236.0, 255.7	243.7, 264.6	99.81, 110.11	96.46, 106.58

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Platelets (G/L)						
Day 91/Discharge Ambulatory	n	79	41	39		
	Geometric LS Mean (CV%)	246.8	241.7	253.1	102.11 (15.85)	97.51 (15.85)
	95% CI	238.2, 255.8	230.1, 253.9	240.6, 266.2	96.15, 108.45	91.73, 103.66

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Prostaglandin F2 Alpha (pg/mg creat)						
Day 5	n	73	40	36		
	Geometric LS Mean (CV%)	227.81	267.36	243.00	85.21 (22.35)	93.75 (22.35)
	95% CI	216.33, 239.89	249.44, 286.58	225.76, 261.56	78.17, 92.87	85.71, 102.54
Day 30	n	73	40	36		
	Geometric LS Mean (CV%)	284.53	316.49	287.85	89.90 (31.74)	98.85 (31.74)
	95% CI	264.63, 305.93	287.13, 348.85	259.62, 319.15	79.66, 101.45	87.16, 112.10
Day 60	n	73	40	36		
	Geometric LS Mean (CV%)	281.41	303.19	278.03	92.82 (31.71)	101.22 (31.71)
	95% CI	261.74, 302.55	275.09, 334.16	250.78, 308.23	82.26, 104.73	89.26, 114.77

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Prostaglandin F2 Alpha (pg/mg creat)						
Day 90	n	73	40	36		
	Geometric LS Mean (CV%)	269.57	304.74	271.37	88.46 (28.14)	99.34 (28.14)
	95% CI	252.71, 287.57	279.42, 332.35	247.52, 297.51	79.43, 98.52	88.80, 111.12

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
11-Dehydro-Thromboxane B2 (pg/mg creat)						
Day 5	n	73	40	36		
	Geometric LS Mean (CV%)	534.63	639.70	518.45	83.57 (26.18)	103.12 (26.18)
	95% CI	503.35, 567.84	590.05, 693.54	475.95, 564.73	75.61, 92.38	92.91, 114.46
Day 30	n	73	40	36		
	Geometric LS Mean (CV%)	446.61	476.70	463.98	93.69 (44.80)	96.25 (44.80)
	95% CI	404.05, 493.65	416.81, 545.19	402.53, 534.82	79.32, 110.65	80.94, 114.47
Day 60	n	73	40	36		
	Geometric LS Mean (CV%)	426.61	420.87	396.99	101.37 (58.01)	107.46 (58.01)
	95% CI	376.07, 483.95	355.40, 498.38	331.95, 474.77	82.20, 125.00	86.40, 133.66

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2 Analysis of Risk Markers - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
11-Dehydro-Thromboxane B2 (pg/mg creat)						
Day 90	n	73	40	36		
	Geometric LS Mean (CV%)	409.96	432.41	457.44	94.81 (56.76)	89.62 (56.76)
	95% CI	362.25, 463.97	366.32, 510.44	383.78, 545.22	77.19, 116.45	72.35, 111.02

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
11-Dehydro-Thromboxane B2 (pg/mg creat)						
Day 5	n	73	40	35		
	Geometric LS Mean (CV%)	537.76	643.06	513.43	83.63 (25.80)	104.74 (25.80)
	95% CI	506.75, 570.68	593.84, 696.37	471.39, 559.22	75.76, 92.31	94.42, 116.19
Day 30	n	73	40	35		
	Geometric LS Mean (CV%)	449.07	479.66	474.97	93.62 (44.57)	94.55 (44.57)
	95% CI	406.49, 496.10	419.69, 548.19	411.58, 548.13	79.33, 110.49	79.45, 112.51

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix: 15.3.3.1

Study ID: ZRHM-REXA-08-US

Program: t_anl_dtx.sas

Status: Final

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**Table 15.2.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
11-Dehydro-Thromboxane B2 (pg/mg creat)						
Day 60	n	73	39	35		
	Geometric LS Mean (CV%)	429.22	422.37	402.49	101.62 (58.40)	106.64 (58.40)
	95% CI	378.09, 487.26	355.64, 501.61	335.40, 482.99	82.16, 125.70	85.46, 133.07
Day 90	n	73	39	35		
	Geometric LS Mean (CV%)	412.39	433.83	460.11	95.06 (57.21)	89.63 (57.21)
	95% CI	364.08, 467.10	366.41, 513.66	384.66, 550.35	77.14, 117.13	72.11, 111.40

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix: 15.3.3.1

Study ID: ZRHM-REXA-08-US

Program: t_anl_dtx.sas

Status: Final

21SEP15

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**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 1**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg)	Baseline	n	74	34		22	
		Missing, n(%)	1 (1.3)	1 (2.9)		2 (8.3)	
		Mean (SD)	118.6 (9.50)	119.9 (9.58)		112.6 (9.29)	
		95% CI	116.3, 120.8	116.5, 123.2		108.4, 116.8	
		Median	118.5	118.5		113.5	
		Q25, Q75	110.0, 125.0	114.0, 125.0		107.0, 120.0	
		Min, Max	100, 152	90, 139		96, 126	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 1**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg) Day 1	n	74	74	34	34	20	20
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	4 (16.7)	4 (16.7)
	Mean (SD)	115.2 (8.99)	-3.0 (6.51)	115.0 (8.49)	-3.4 (6.56)	110.8 (10.60)	-3.8 (7.90)
	95% CI	113.0, 117.3	-4.6, -1.4	112.0, 118.0	-5.7, -1.0	105.8, 115.8	-7.6, -0.1
	Median	114.0	-2.4	115.5	-3.8	109.0	-3.3
	Q25, Q75	108.0, 122.0	-7.6, 1.7	111.0, 120.0	-6.8, 0.8	103.5, 118.5	-6.3, 1.3
	Min, Max	97, 137	-21, 10	91, 138	-19, 11	87, 129	-26, 8

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 1**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg) Day 2	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	114.5 (9.74)	-3.4 (6.41)	113.6 (8.08)	-4.5 (6.74)	111.7 (8.58)	-1.3 (7.30)
	95% CI	112.2, 116.8	-5.0, -1.9	110.8, 116.5	-6.9, -2.1	108.0, 115.3	-4.4, 1.8
	Median	114.0	-4.5	114.0	-6.2	111.0	-1.9
	Q25, Q75	107.0, 120.0	-8.3, 0.9	110.0, 120.0	-8.8, 1.8	106.5, 117.0	-5.6, 1.8
	Min, Max	97, 139	-15, 13	94, 131	-15, 11	96, 130	-14, 14

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 1**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg) Day 3	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	114.9 (8.55)	-3.0 (6.90)	117.9 (9.09)	-1.0 (6.56)	109.3 (7.51)	-3.4 (6.76)
	95% CI	112.9, 116.9	-4.7, -1.4	114.6, 121.1	-3.4, 1.3	106.1, 112.5	-6.3, -0.5
	Median	115.0	-3.5	118.0	-1.7	109.5	-4.4
	Q25, Q75	110.0, 120.0	-7.8, 1.8	112.0, 123.0	-4.3, 2.4	104.0, 114.0	-8.1, 1.2
	Min, Max	97, 135	-21, 14	97, 133	-15, 13	90, 124	-16, 10

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 1**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg) Day 4	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	113.9 (8.36)	-3.9 (6.32)	116.6 (8.08)	-2.0 (6.49)	108.8 (8.55)	-3.9 (7.43)
	95% CI	111.9, 115.9	-5.4, -2.4	113.8, 119.5	-4.3, 0.3	105.1, 112.4	-7.1, -0.7
	Median	113.0	-4.0	116.0	-2.6	107.0	-5.2
	Q25, Q75	109.0, 119.0	-8.1, 0.9	112.0, 121.0	-5.4, 2.5	103.5, 118.0	-8.6, 2.9
	Min, Max	96, 139	-24, 9	95, 137	-17, 12	93, 126	-17, 13

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 1**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg) Day 5	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	116.7 (10.18)	-1.6 (6.91)	118.6 (9.97)	-0.4 (7.45)	112.1 (8.87)	-0.9 (8.06)
	95% CI	114.3, 119.1	-3.3, 0.0	115.1, 122.1	-3.0, 2.3	108.3, 115.9	-4.4, 2.5
	Median	117.0	-2.4	117.5	-0.4	112.5	0.4
	Q25, Q75	110.0, 122.0	-6.7, 3.9	111.0, 124.0	-6.0, 6.3	106.0, 119.0	-6.1, 4.2
	Min, Max	94, 150	-18, 21	97, 147	-17, 16	93, 126	-20, 15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 1**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg)	Day 6/Discharge n	75	75	35	34	24	24
	Missing, n(%)	0	0	0	1 (2.9)	0	0
	Mean (SD)	117.1 (10.13)	-1.2 (7.38)	119.5 (10.72)	0.1 (8.26)	114.0 (9.12)	0.8 (7.97)
	95% CI	114.7, 119.5	-2.9, 0.5	115.7, 123.2	-2.8, 3.0	110.1, 117.9	-2.6, 4.2
	Median	117.0	-0.8	118.0	-1.5	112.5	-1.9
	Q25, Q75	110.0, 123.0	-5.6, 4.6	112.0, 126.0	-4.3, 5.4	108.5, 119.0	-4.0, 5.7
	Min, Max	91, 151	-26, 12	96, 143	-20, 23	96, 135	-12, 17

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 1**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg)	Baseline	n	74	34		22	
		Missing, n(%)	1 (1.3)	1 (2.9)		2 (8.3)	
		Mean (SD)	71.8 (7.91)	73.0 (6.94)		69.4 (7.44)	
		95% CI	69.9, 73.7	70.5, 75.4		66.0, 72.7	
		Median	72.5	71.0		70.5	
		Q25, Q75	67.0, 76.0	69.0, 78.0		63.0, 75.0	
		Min, Max	52, 89	54, 88		55, 80	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 1**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg) Day 1	n	74	74	34	34	20	20
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	4 (16.7)	4 (16.7)
	Mean (SD)	68.4 (8.03)	-4.8 (9.39)	69.3 (7.74)	-5.1 (8.48)	67.1 (9.47)	-6.9 (10.73)
	95% CI	66.5, 70.4	-7.1, -2.6	66.5, 72.0	-8.1, -2.1	62.6, 71.6	-12.0, -1.9
	Median	67.5	-4.5	70.5	-4.0	65.0	-8.6
	Q25, Q75	64.0, 74.0	-11.0, 2.7	64.0, 75.0	-12.2, 1.9	60.0, 72.5	-12.8, 1.4
	Min, Max	40, 89	-32, 12	55, 85	-28, 7	53, 89	-28, 15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 1**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg) Day 2	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	68.6 (8.15)	-4.3 (9.42)	68.7 (8.41)	-5.9 (9.19)	67.1 (7.57)	-4.2 (11.75)
	95% CI	66.7, 70.5	-6.6, -2.1	65.8, 71.7	-9.2, -2.7	63.8, 70.3	-9.2, 0.8
	Median	68.0	-4.2	66.5	-3.2	69.5	-5.7
	Q25, Q75	64.0, 73.0	-10.7, 0.0	63.0, 76.0	-10.0, 0.0	61.0, 71.0	-10.7, 1.2
	Min, Max	53, 91	-25, 20	52, 88	-28, 10	54, 84	-29, 22

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 1**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg) Day 3	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	69.3 (7.22)	-3.2 (9.62)	71.5 (7.93)	-2.1 (8.19)	66.7 (8.25)	-5.1 (9.15)
	95% CI	67.6, 71.0	-5.5, -0.9	68.7, 74.3	-5.1, 0.8	63.2, 70.2	-9.0, -1.1
	Median	69.0	-2.6	71.0	-0.6	66.5	-5.7
	Q25, Q75	64.0, 75.0	-9.6, 4.2	66.0, 76.0	-7.0, 3.9	60.5, 71.0	-8.5, 0.8
	Min, Max	53, 91	-26, 23	52, 90	-25, 15	52, 84	-32, 13

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 1**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg) Day 4	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	67.6 (6.37)	-5.6 (8.87)	69.8 (7.84)	-4.3 (9.46)	65.3 (7.57)	-6.9 (9.75)
	95% CI	66.0, 69.1	-7.7, -3.5	67.0, 72.6	-7.7, -1.0	62.0, 68.5	-11.1, -2.7
	Median	68.0	-6.8	69.5	-4.2	64.0	-5.7
	Q25, Q75	63.0, 73.0	-10.3, 0.0	64.0, 74.0	-7.2, 2.4	60.0, 70.0	-12.1, -0.7
	Min, Max	51, 90	-27, 17	52, 86	-27, 11	55, 81	-25, 10

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 1**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg) Day 5	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	69.4 (7.56)	-3.1 (9.29)	71.6 (9.32)	-1.9 (10.56)	68.5 (8.09)	-2.3 (10.90)
	95% CI	67.6, 71.2	-5.3, -0.9	68.3, 74.9	-5.7, 1.8	65.0, 72.0	-7.0, 2.3
	Median	68.0	-3.6	72.0	-1.5	67.5	-4.2
	Q25, Q75	64.0, 74.0	-8.1, 2.8	65.0, 76.0	-6.6, 5.6	62.0, 74.5	-8.0, 6.3
	Min, Max	53, 90	-28, 25	58, 93	-29, 16	57, 86	-25, 21

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 1**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg) Day 6/Discharge n Confinement		75	75	35	34	24	24
	Missing, n(%)	0	0	0	1 (2.9)	0	0
	Mean (SD)	70.2 (7.71)	-1.8 (11.61)	72.7 (7.15)	0.0 (9.09)	69.3 (6.63)	-1.1 (9.60)
	95% CI	68.4, 72.0	-4.5, 0.9	70.2, 75.2	-3.3, 3.2	66.4, 72.1	-5.2, 3.0
	Median	71.0	-3.1	73.0	1.3	69.0	-0.7
	Q25, Q75	64.0, 75.0	-9.1, 4.3	67.0, 78.0	-4.8, 5.8	65.0, 73.0	-5.1, 4.4
	Min, Max	54, 93	-24, 30	59, 91	-27, 17	59, 85	-25, 21

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 2**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg)	Baseline	n	39	33		11	
		Missing, n(%)	1 (2.5)	1 (2.9)		2 (15.4)	
		Mean (SD)	119.6 (8.53)	119.8 (9.90)		116.8 (10.31)	
		95% CI	116.8, 122.4	116.3, 123.4		109.8, 123.8	
		Median	119.0	118.0		117.0	
		Q25, Q75	114.0, 125.0	114.0, 124.0		112.0, 124.0	
		Min, Max	104, 135	90, 139		96, 135	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 2**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg) Day 30	n	40	40	34	34	13	13
	Mean (SD)	117.6 (10.81)	-1.9 (7.32)	117.2 (11.49)	-1.9 (7.49)	115.4 (9.41)	-0.5 (9.99)
	95% CI	114.1, 121.1	-4.3, 0.5	113.1, 121.2	-4.5, 0.8	109.7, 121.1	-6.5, 5.6
	Median	118.5	-3.2	115.0	-2.0	113.0	-2.6
	Q25, Q75	110.0, 124.0	-7.0, 3.3	110.0, 124.0	-6.6, 3.3	111.0, 118.0	-7.5, 7.5
	Min, Max	92, 148	-16, 13	96, 155	-16, 13	102, 137	-15, 18

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 2**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg) Baseline	n	39		33		11	
	Missing, n(%)	1 (2.5)		1 (2.9)		2 (15.4)	
	Mean (SD)	71.9 (7.09)		73.2 (7.11)		72.7 (8.56)	
	95% CI	69.6, 74.3		70.6, 75.8		66.9, 78.5	
	Median	72.0		71.0		73.0	
	Q25, Q75	68.0, 76.0		69.0, 78.0		70.0, 79.0	
	Min, Max	55, 88		54, 88		55, 84	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 2**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg) Day 30	n	40	40	34	34	13	13
	Mean (SD)	70.4 (8.14)	-2.3 (11.12)	71.3 (9.45)	-2.5 (11.21)	68.1 (10.75)	-5.9 (14.00)
	95% CI	67.7, 73.0	-5.9, 1.3	67.9, 74.6	-6.4, 1.5	61.5, 74.6	-14.4, 2.6
	Median	69.5	-2.1	74.5	-0.6	68.0	-6.9
	Q25, Q75	65.0, 74.5	-10.1, 3.1	63.0, 78.0	-8.5, 5.4	64.0, 75.0	-16.7, 3.7
	Min, Max	54, 93	-27, 25	57, 89	-32, 17	44, 85	-28, 24

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 3**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg)	Baseline	n	37	34		8	
		Missing, n(%)	2 (5.1)	1 (2.9)		4 (33.3)	
		Mean (SD)	118.5 (8.78)	120.0 (9.80)		116.3 (11.82)	
		95% CI	115.5, 121.5	116.6, 123.5		106.3, 126.2	
		Median	119.0	118.5		117.0	
		Q25, Q75	110.0, 124.0	114.0, 125.0		109.5, 123.0	
		Min, Max	100, 134	90, 139		96, 135	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 3**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg) Day 60	n	39	39	35	35	12	12
	Mean (SD)	117.5 (12.92)	-0.9 (9.68)	116.7 (10.96)	-2.3 (8.21)	114.2 (7.98)	-0.1 (8.18)
	95% CI	113.3, 121.7	-4.0, 2.3	112.9, 120.6	-5.2, 0.6	109.0, 119.3	-5.3, 5.2
	Median	118.0	-0.8	115.0	-1.7	112.5	1.2
	Q25, Q75	109.0, 126.0	-6.9, 5.0	109.0, 124.0	-8.8, 1.7	110.0, 119.0	-8.8, 4.9
	Min, Max	85, 152	-20, 27	92, 140	-21, 19	103, 130	-10, 16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 3**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg)	Baseline	n	37	34		8	
		Missing, n(%)	2 (5.1)	1 (2.9)		4 (33.3)	
		Mean (SD)	70.8 (7.61)	73.4 (7.13)		72.4 (9.77)	
		95% CI	68.2, 73.3	70.9, 76.0		64.2, 80.6	
		Median	71.0	72.0		74.5	
		Q25, Q75	66.0, 76.0	69.0, 80.0		66.5, 79.0	
		Min, Max	52, 82	54, 88		55, 84	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 3**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg) Day 60	n	39	39	35	35	12	12
	Mean (SD)	69.5 (10.11)	-1.5 (13.31)	69.5 (11.00)	-5.1 (13.48)	69.1 (8.81)	-3.5 (10.84)
	95% CI	66.2, 72.8	-5.8, 2.9	65.7, 73.4	-9.8, -0.5	63.4, 74.7	-10.5, 3.4
	Median	67.0	-1.6	67.0	-2.9	68.0	-2.0
	Q25, Q75	63.0, 77.0	-12.2, 5.5	62.0, 78.0	-15.0, 3.9	63.5, 75.5	-13.6, 6.6
	Min, Max	52, 96	-26, 30	49, 91	-41, 25	54, 84	-21, 9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 4**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg)	Baseline	n	45	31		6	
		Missing, n(%)	2 (4.3)	1 (3.1)		3 (33.3)	
		Mean (SD)	118.8 (8.84)	119.7 (9.74)		116.8 (13.10)	
		95% CI	116.1, 121.5	116.1, 123.4		103.0, 130.6	
		Median	119.0	119.0		117.0	
		Q25, Q75	110.0, 125.0	113.0, 125.0		112.0, 124.0	
		Min, Max	100, 135	90, 139		96, 135	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 4**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg) Day 91/Discharge Ambulatory	n	47	47	32	32	9	9
	Mean (SD)	116.8 (11.88)	-1.8 (6.79)	117.9 (9.76)	-1.1 (7.40)	114.1 (5.85)	-0.9 (10.49)
	95% CI	113.2, 120.3	-3.9, 0.2	114.3, 121.5	-3.8, 1.6	109.6, 118.7	-9.0, 7.2
	Median	116.0	-1.7	116.0	-1.3	111.0	-5.3
	Q25, Q75	109.0, 125.0	-6.0, 4.9	112.0, 125.5	-5.9, 4.0	110.0, 117.0	-7.5, 2.6
	Min, Max	87, 144	-19, 9	97, 136	-18, 15	108, 125	-11, 17

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 4**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg) Baseline	n	45		31		6	
	Missing, n(%)	2 (4.3)		1 (3.1)		3 (33.3)	
	Mean (SD)	71.3 (7.83)		73.5 (7.42)		71.2 (11.09)	
	95% CI	68.9, 73.7		70.7, 76.3		59.5, 82.9	
	Median	71.0		71.0		74.0	
	Q25, Q75	66.0, 76.0		69.0, 80.0		61.0, 79.0	
	Min, Max	52, 88		54, 88		55, 84	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.1 Descriptive Statistics of Blood Pressure (mmHg) - PP Set****Product Use Time Period: Period 4**

Parameter (units) Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg) Day 91/Discharge Ambulatory	n	47	47	32	32	9	9
	Mean (SD)	70.1 (10.64)	-1.5 (13.03)	71.0 (8.89)	-3.1 (11.46)	68.6 (6.01)	-4.6 (14.42)
	95% CI	66.9, 73.3	-5.3, 2.4	67.7, 74.2	-7.3, 1.1	63.9, 73.2	-15.7, 6.6
	Median	71.0	-3.4	71.0	-1.3	70.0	-8.5
	Q25, Q75	62.0, 76.0	-8.8, 6.9	63.5, 75.0	-9.8, 5.8	64.0, 72.0	-15.3, -3.8
	Min, Max	44, 97	-33, 35	53, 91	-28, 17	57, 76	-17, 27

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg)	Baseline	n	78		40		37	
		Missing, n(%)	2 (2.5)		1 (2.4)		2 (5.1)	
		Mean (SD)	118.5 (9.38)		119.3 (9.88)		112.9 (9.52)	
		95% CI	116.4, 120.7		116.1, 122.5		109.7, 116.2	
		Median	118.5		118.0		113.0	
		Q25, Q75	110.0, 125.0		113.0, 125.0		107.0, 120.0	
		Min, Max	100, 152		90, 139		96, 135	
	Day 1	n	78	78	40	40	29	29
		Missing, n(%)	2 (2.5)	2 (2.5)	1 (2.4)	1 (2.4)	10 (25.6)	10 (25.6)
		Mean (SD)	115.3 (9.14)	-2.8 (6.67)	114.8 (8.12)	-3.1 (6.96)	111.1 (10.02)	-4.0 (6.81)
		95% CI	113.2, 117.4	-4.4, -1.3	112.2, 117.5	-5.4, -0.8	107.3, 115.0	-6.6, -1.4
		Median	114.0	-2.4	115.5	-3.3	109.0	-3.3
		Q25, Q75	108.0, 122.0	-7.6, 1.7	111.0, 119.0	-6.9, 0.9	105.0, 118.0	-6.3, -0.8
		Min, Max	97, 137	-21, 14	91, 138	-19, 13	87, 132	-26, 8

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg)	Day 2	n	79	79	40	40	34	34
		Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
		Mean (SD)	114.4 (9.64)	-3.5 (6.39)	113.4 (8.30)	-4.3 (7.28)	110.9 (9.09)	-1.9 (7.37)
		95% CI	112.2, 116.6	-5.0, -2.1	110.6, 116.1	-6.7, -1.9	107.6, 114.1	-4.6, 0.7
		Median	114.0	-4.7	114.0	-6.3	110.0	-2.8
		Q25, Q75	107.0, 120.0	-8.3, 0.9	108.0, 119.0	-8.8, 0.5	105.0, 116.0	-8.5, 2.8
		Min, Max	97, 139	-15, 13	94, 131	-15, 17	96, 131	-14, 14
	Day 3	n	79	79	40	40	34	34
		Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
		Mean (SD)	114.6 (8.49)	-3.2 (6.81)	117.0 (9.09)	-1.4 (6.62)	110.3 (9.32)	-2.5 (7.38)
		95% CI	112.7, 116.6	-4.8, -1.7	114.0, 119.9	-3.5, 0.8	107.0, 113.6	-5.1, 0.2
		Median	114.0	-3.8	117.5	-1.8	110.0	-3.9
		Q25, Q75	109.0, 120.0	-7.8, 1.7	111.5, 122.5	-6.3, 3.0	104.0, 115.0	-8.0, 3.3
		Min, Max	97, 135	-21, 14	97, 133	-15, 13	90, 130	-16, 15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg)	Day 4	n	79	79	40	40	34	34
		Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
		Mean (SD)	113.8 (8.20)	-4.0 (6.37)	116.4 (7.92)	-1.8 (6.42)	109.3 (9.63)	-3.3 (8.11)
		95% CI	111.9, 115.6	-5.4, -2.5	113.8, 119.0	-3.9, 0.3	105.9, 112.7	-6.2, -0.4
		Median	113.0	-4.0	116.0	-2.6	107.0	-5.0
		Q25, Q75	109.0, 119.0	-8.5, 0.9	112.0, 121.0	-5.3, 3.5	103.0, 118.0	-8.8, 3.1
		Min, Max	96, 139	-24, 9	95, 137	-17, 12	93, 127	-17, 13
	Day 5	n	79	79	40	40	34	34
		Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
		Mean (SD)	116.2 (10.11)	-2.0 (6.97)	118.6 (9.94)	0.0 (7.31)	112.8 (8.31)	-0.2 (7.59)
		95% CI	113.9, 118.6	-3.6, -0.3	115.4, 121.8	-2.4, 2.4	109.8, 115.7	-2.9, 2.5
		Median	116.0	-2.5	117.5	0.0	112.5	0.4
		Q25, Q75	109.0, 122.0	-6.8, 3.8	110.5, 124.0	-5.7, 6.2	107.0, 119.0	-5.2, 5.1
		Min, Max	94, 150	-18, 21	97, 147	-17, 16	93, 126	-20, 15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg)	Day 6/Discharge Confinement	n	79	79	41	40	39	37
		Missing, n(%)	1 (1.3)	1 (1.3)	0	1 (2.4)	0	2 (5.1)
		Mean (SD)	117.0 (9.95)	-1.3 (7.21)	118.9 (10.80)	0.1 (8.09)	113.2 (8.70)	0.1 (8.60)
		95% CI	114.7, 119.3	-2.9, 0.4	115.4, 122.4	-2.6, 2.7	110.3, 116.0	-2.8, 3.0
		Median	117.0	-0.8	118.0	-1.6	112.0	-1.9
		Q25, Q75	110.0, 121.0	-4.8, 4.5	112.0, 124.0	-4.7, 4.7	107.0, 118.0	-4.8, 3.3
		Min, Max	91, 151	-26, 12	96, 143	-20, 23	95, 135	-15, 17
	Day 30	n	79	79	41	40	39	37
		Missing, n(%)	1 (1.3)	1 (1.3)	0	1 (2.4)	0	2 (5.1)
		Mean (SD)	117.7 (11.14)	-0.7 (8.01)	117.1 (11.24)	-1.6 (7.06)	112.6 (10.25)	-0.4 (9.61)
		95% CI	115.2, 120.2	-2.6, 1.1	113.5, 120.7	-3.9, 0.7	109.2, 116.0	-3.7, 2.8
		Median	118.0	-0.8	115.0	-1.7	111.0	-1.8
		Q25, Q75	110.0, 126.0	-5.6, 4.3	110.0, 124.0	-5.8, 3.2	107.0, 115.0	-7.1, 4.4
		Min, Max	92, 148	-20, 24	96, 155	-16, 13	92, 148	-15, 29

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg)	Day 60	n	79	79	41	40	39	37
		Missing, n(%)	1 (1.3)	1 (1.3)	0	1 (2.4)	0	2 (5.1)
		Mean (SD)	116.8 (11.82)	-1.5 (9.02)	115.9 (11.55)	-2.6 (8.35)	113.5 (8.23)	0.4 (8.26)
		95% CI	114.1, 119.5	-3.5, 0.6	112.2, 119.5	-5.3, 0.1	110.8, 116.2	-2.4, 3.2
		Median	116.0	-1.6	114.0	-1.3	113.0	0.0
		Q25, Q75	108.0, 126.0	-6.4, 3.6	109.0, 124.0	-8.1, 1.8	108.0, 117.0	-7.0, 5.1
		Min, Max	85, 152	-30, 27	91, 140	-21, 19	99, 134	-13, 21

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Systolic blood Pressure (mmHg)	Day 91/Discharge n Ambulatory	n	79	79	41	40	39	37
		Missing, n(%)	1 (1.3)	1 (1.3)	0	1 (2.4)	0	2 (5.1)
		Mean (SD)	117.6 (10.92)	-0.9 (6.81)	117.6 (9.82)	-1.1 (6.77)	115.3 (9.56)	2.3 (12.11)
		95% CI	115.1, 120.1	-2.5, 0.7	114.4, 120.7	-3.3, 1.1	112.1, 118.4	-1.7, 6.4
		Median	117.0	-0.8	116.0	-1.2	114.0	-0.9
		Q25, Q75	110.0, 125.0	-5.3, 4.9	112.0, 125.0	-4.9, 3.0	109.0, 121.0	-5.2, 8.4
		Min, Max	87, 144	-19, 14	97, 136	-18, 15	95, 139	-22, 38

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg)	Baseline	n	78		40		37	
		Missing, n(%)	2 (2.5)		1 (2.4)		2 (5.1)	
		Mean (SD)	71.7 (7.82)		72.7 (7.97)		69.2 (7.96)	
		95% CI	69.9, 73.5		70.1, 75.3		66.5, 71.9	
		Median	72.0		71.0		71.0	
		Q25, Q75	67.0, 76.0		67.5, 79.0		63.0, 75.0	
		Min, Max	52, 89		54, 90		53, 84	
	Day 1	n	78	78	40	40	29	29
		Missing, n(%)	2 (2.5)	2 (2.5)	1 (2.4)	1 (2.4)	10 (25.6)	10 (25.6)
		Mean (SD)	68.5 (8.14)	-4.6 (9.51)	68.7 (7.48)	-5.3 (8.99)	66.9 (8.17)	-6.0 (9.92)
		95% CI	66.6, 70.4	-6.8, -2.4	66.3, 71.2	-8.2, -2.4	63.7, 70.1	-9.8, -2.1
		Median	67.5	-4.5	69.0	-4.3	67.0	-6.9
		Q25, Q75	63.0, 74.0	-10.7, 2.7	63.5, 73.5	-12.3, 1.7	61.0, 71.0	-12.2, 0.0
		Min, Max	40, 89	-32, 16	55, 85	-28, 13	53, 89	-28, 15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg)	Day 2	n	79	79	40	40	34	34
		Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
		Mean (SD)	68.5 (8.14)	-4.3 (9.45)	69.0 (8.33)	-4.8 (12.09)	65.5 (9.06)	-5.6 (11.47)
		95% CI	66.6, 70.4	-6.5, -2.1	66.3, 71.7	-8.7, -0.9	62.3, 68.7	-9.6, -1.5
		Median	68.0	-4.3	67.0	-3.3	64.5	-6.8
		Q25, Q75	64.0, 73.0	-10.7, 0.0	63.0, 76.0	-11.1, 0.0	59.0, 71.0	-11.3, 0.0
		Min, Max	53, 91	-25, 20	52, 88	-28, 47	47, 90	-29, 22
	Day 3	n	79	79	40	40	34	34
		Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
		Mean (SD)	69.2 (7.09)	-3.3 (9.45)	70.8 (7.99)	-2.6 (8.29)	66.3 (9.10)	-4.6 (9.66)
		95% CI	67.5, 70.8	-5.4, -1.1	68.2, 73.4	-5.3, 0.1	63.1, 69.5	-8.0, -1.2
		Median	68.0	-2.7	71.0	-1.5	65.5	-5.7
		Q25, Q75	64.0, 75.0	-9.6, 3.7	65.5, 76.0	-8.0, 3.9	59.0, 72.0	-10.3, 1.9
		Min, Max	53, 91	-26, 23	52, 90	-25, 15	52, 90	-32, 13

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg)	Day 4	n	79	79	40	40	34	34
		Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
		Mean (SD)	67.6 (6.34)	-5.4 (9.06)	69.4 (8.16)	-4.5 (8.93)	64.0 (8.89)	-7.7 (10.96)
		95% CI	66.1, 69.0	-7.5, -3.4	66.7, 72.1	-7.4, -1.5	60.9, 67.1	-11.6, -3.8
		Median	68.0	-6.8	68.5	-4.2	62.5	-7.1
		Q25, Q75	63.0, 73.0	-10.5, 0.0	63.5, 74.5	-8.2, 1.9	57.0, 68.0	-13.9, 0.0
		Min, Max	51, 90	-27, 17	52, 86	-27, 11	50, 89	-29, 10
	Day 5	n	79	79	40	40	34	34
		Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
		Mean (SD)	69.2 (7.49)	-3.3 (9.21)	71.6 (9.10)	-1.5 (10.34)	67.8 (8.32)	-2.3 (10.22)
		95% CI	67.5, 70.9	-5.4, -1.2	68.6, 74.5	-4.8, 1.9	64.8, 70.7	-5.9, 1.3
		Median	68.0	-3.6	71.5	-1.5	67.5	-1.3
		Q25, Q75	64.0, 74.0	-8.6, 2.8	65.0, 76.5	-5.9, 5.4	62.0, 73.0	-8.0, 4.5
		Min, Max	53, 90	-28, 25	58, 93	-29, 18	50, 86	-25, 21

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg)	Day 6/Discharge Confinement	n	79	79	41	40	39	37
		Missing, n(%)	1 (1.3)	1 (1.3)	0	1 (2.4)	0	2 (5.1)
		Mean (SD)	70.0 (7.55)	-1.9 (11.44)	72.4 (7.59)	0.0 (9.08)	68.6 (7.38)	-1.3 (10.79)
		95% CI	68.3, 71.8	-4.5, 0.7	70.0, 74.9	-3.0, 2.9	66.2, 71.1	-4.9, 2.4
		Median	70.0	-2.5	72.0	1.3	69.0	-1.4
		Q25, Q75	64.0, 75.0	-9.1, 3.8	65.0, 78.0	-5.4, 5.0	65.0, 72.0	-7.5, 4.8
		Min, Max	54, 93	-24, 30	59, 91	-27, 18	49, 86	-25, 26
	Day 30	n	79	79	41	40	39	37
		Missing, n(%)	1 (1.3)	1 (1.3)	0	1 (2.4)	0	2 (5.1)
		Mean (SD)	70.3 (8.22)	-1.5 (12.40)	71.3 (9.63)	-1.7 (10.76)	67.8 (8.94)	-2.5 (13.84)
		95% CI	68.4, 72.2	-4.4, 1.3	68.2, 74.4	-5.2, 1.7	64.8, 70.7	-7.2, 2.1
		Median	70.0	-3.4	69.0	-0.6	68.0	-3.8
		Q25, Q75	65.0, 76.0	-10.7, 6.1	63.0, 78.0	-7.3, 5.4	62.0, 73.0	-10.8, 3.8
		Min, Max	53, 93	-27, 39	57, 89	-32, 17	44, 86	-28, 32

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg)	Day 60	n	79	79	41	40	39	37
		Missing, n(%)	1 (1.3)	1 (1.3)	0	1 (2.4)	0	2 (5.1)
		Mean (SD)	69.9 (8.75)	-2.2 (12.57)	68.8 (11.30)	-5.5 (12.98)	68.5 (8.33)	-1.5 (11.49)
		95% CI	67.9, 71.9	-5.0, 0.7	65.1, 72.4	-9.6, -1.3	65.7, 71.2	-5.4, 2.3
		Median	69.0	-3.3	67.0	-3.0	68.0	-2.7
		Q25, Q75	64.0, 76.0	-10.7, 4.2	61.0, 78.0	-14.4, 2.6	63.0, 73.0	-9.7, 6.3
		Min, Max	52, 96	-26, 30	49, 91	-41, 25	54, 97	-21, 29

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Diastolic blood Pressure (mmHg)	Day 91/Discharge n Ambulatory	n	79	79	41	40	39	37
		Missing, n(%)	1 (1.3)	1 (1.3)	0	1 (2.4)	0	2 (5.1)
		Mean (SD)	70.7 (9.35)	-1.2 (12.33)	70.2 (8.95)	-3.2 (10.57)	70.4 (8.35)	2.0 (17.08)
		95% CI	68.5, 72.8	-4.1, 1.6	67.4, 73.1	-6.6, 0.3	67.7, 73.2	-3.7, 7.8
		Median	71.0	-3.5	71.0	-1.4	70.0	0.0
		Q25, Q75	65.0, 76.0	-7.9, 5.6	63.0, 75.0	-9.8, 5.0	65.0, 76.0	-8.5, 9.5
		Min, Max	44, 97	-33, 35	53, 91	-28, 17	52, 90	-35, 48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 1**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Glucose (mg/dL)	Baseline	n	75		35		24	
		Geometric Mean (CV%)	93.9 (7.47)		93.5 (8.07)		94.2 (12.21)	
		95% CI of Geometric Mean	92.2, 95.6		90.9, 96.1		89.5, 99.2	
		Median	93.0		93.0		90.5	
		Q25, Q75	89.0, 98.0		88.0, 99.0		86.0, 101.0	
		Min, Max	83, 118		83, 116		81, 132	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 1**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Glucose (mg/dL)	Day 6/Discharge Confinement	n	75	75	34	34	24	24
		Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
		Geometric Mean (CV%)	89.0 (9.28)		84.7 (6.38)		89.6 (11.05)	
		95% CI of Geometric Mean	87.1, 90.9		82.8, 86.6		85.5, 93.9	
		Median	88.0	-5.0	85.0	-9.6	90.0	-4.4
		Q25, Q75	84.0, 93.0	-10.6, 0.0	81.0, 87.0	-14.0, -5.7	83.0, 95.5	-7.1, 1.2
		Min, Max	75, 139	-23, 53	74, 97	-21, 8	72, 115	-25, 10

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 1**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Triglycerides (mg/dL)	Baseline	n	75		35		24	
		Mean (SD)	137.1 (70.67)		128.0 (42.68)		131.7 (48.10)	
		95% CI	120.8, 153.4		113.3, 142.7		111.4, 152.1	
		Median	122.0		118.0		116.0	
		Q25, Q75	90.0, 156.0		94.0, 169.0		97.0, 173.0	
		Min, Max	54, 438		68, 219		71, 238	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 1**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Triglycerides (mg/dL)	Day 6/Discharge Confinement	n	75	75	34	34	24	24
		Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
		Mean (SD)	123.8 (70.37)	-7.9 (23.42)	112.7 (49.44)	-11.6 (20.11)	135.3 (61.22)	6.0 (39.99)
		95% CI	107.6, 140.0	-13.3, -2.4	95.4, 130.0	-18.7, -4.6	109.4, 161.2	-10.9, 22.9
		Median	94.0	-8.5	96.0	-12.5	131.5	-10.3
		Q25, Q75	80.0, 146.0	-23.3, 4.4	74.0, 153.0	-22.6, 3.8	82.5, 164.0	-23.3, 38.6
		Min, Max	62, 430	-54, 65	60, 232	-56, 38	53, 302	-54, 88

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 1**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Cholesterol (mg/dL)	Baseline	n	75		35		24	
		Mean (SD)	188.3 (38.37)		193.1 (35.07)		203.5 (32.85)	
		95% CI	179.4, 197.2		181.0, 205.2		189.5, 217.4	
		Median	189.0		194.0		198.5	
		Q25, Q75	164.0, 213.0		165.0, 218.0		179.5, 232.0	
		Min, Max	90, 304		129, 273		153, 266	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 1**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Cholesterol (mg/dL)	Day 6/Discharge Confinement	n	75	75	34	34	24	24
		Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
		Mean (SD)	176.3 (35.19)	-5.9 (9.48)	175.7 (34.86)	-9.2 (8.07)	193.8 (36.69)	-4.6 (10.51)
		95% CI	168.2, 184.5	-8.2, -3.7	163.5, 187.9	-12.1, -6.4	178.3, 209.3	-9.1, -0.2
		Median	178.0	-6.1	179.0	-10.3	192.5	-4.0
		Q25, Q75	147.0, 198.0	-11.6, -0.5	148.0, 197.0	-15.5, -3.4	167.5, 223.5	-10.4, 3.0
		Min, Max	77, 278	-30, 21	109, 249	-23, 15	130, 274	-31, 15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
C Reactive Protein (mg/L)	Baseline	n	40		34		13	
		BLOQ, n (%)	3 (7.5)		2 (5.9)		0	
		Geometric Mean	1.324		1.053		1.252	
		(CV%)	(174.6809)		(152.7411)		(231.6514)	
		95% CI of Geometric Mean	0.906, 1.933		0.717, 1.544		0.550, 2.850	
		Median	1.255		0.800		1.240	
		Q25, Q75	0.725, 3.050		0.600, 2.180		0.380, 2.460	
		Min, Max	0.10, 8.98		0.10, 10.00		0.22, 15.80	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
C Reactive Protein (mg/L)	Day 30	n	40	40	34	34	13	13
		BLOQ, n (%)	3 (7.5)		1 (2.9)		2 (15.4)	
		Geometric Mean	1.402		1.483		0.922	
		(CV%)	(188.5213)		(165.4782)		(286.2060)	
		95% CI of Geometric Mean	0.945, 2.079		0.993, 2.215		0.374, 2.269	
		Median	1.845	0.000	1.150	10.535	0.650	-44.494
		Q25, Q75	0.660, 3.130	-33.682, 31.108	0.720, 2.370	-15.854, 103.704	0.470, 3.450	-47.581, 44.970
		Min, Max	0.10, 25.50	-66.13, 434.09	0.10, 31.60	-55.56, 878.33	0.10, 9.51	-78.86, 127.27

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Homocysteine (umol/L)	Baseline	n	40		34		13	
		Geometric Mean	9.900		9.916		10.554	
		(CV%)	(38.9816)		(23.7947)		(39.0267)	
		95% CI of	8.777, 11.166		9.136, 10.763		8.406, 13.251	
		Geometric Mean						
		Median	9.990		9.635		9.790	
		Q25, Q75	7.795, 11.005		8.470, 11.600		8.840, 11.070	
		Min, Max	5.41, 56.40		5.80, 16.60		6.09, 20.76	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Homocysteine (umol/L)	Day 30	n	40	40	34	34	13	13
		Geometric Mean (CV%)	10.053 (35.9363)		9.672 (27.9424)		11.166 (39.6117)	
		95% CI of Geometric Mean	8.992, 11.239		8.789, 10.644		8.865, 14.064	
		Median	9.875	-0.133	9.380	-4.129	11.930	1.406
		Q25, Q75	8.025, 11.445	-6.107, 10.051	7.970, 12.740	-16.193, 9.911	8.240, 14.420	-6.787, 25.447
		Min, Max	5.30, 42.29	-27.37, 46.86	4.89, 15.55	-27.23, 45.63	6.31, 19.87	-24.23, 65.27

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.



Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set

Product Use Time Period: Period 2

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Glucose (mg/dL)	Baseline	n	40		34		13	
		Geometric Mean (CV%)	93.7 (8.41)		93.8 (7.98)		95.1 (14.81)	
		95% CI of Geometric Mean	91.2, 96.3		91.1, 96.5		86.9, 104.0	
		Median	92.5		93.5		94.0	
		Q25, Q75	87.5, 99.5		88.0, 99.0		85.0, 104.0	
		Min, Max	83, 118		83, 116		81, 132	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Glucose (mg/dL)	Day 30	n	40	40	34	34	13	13
		Geometric Mean (CV%)	94.0 (8.47)		92.8 (6.07)		93.8 (15.73)	
		95% CI of Geometric Mean	91.5, 96.7		90.8, 94.8		85.3, 103.2	
		Median	93.0	1.0	93.5	-1.0	91.0	-1.2
		Q25, Q75	89.5, 98.0	-1.1, 3.3	89.0, 98.0	-4.2, 3.4	85.0, 95.0	-6.2, 2.5
		Min, Max	77, 120	-15, 15	81, 103	-16, 10	83, 147	-10, 11

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.



Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set

Product Use Time Period: Period 2

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
LDL Cholesterol (mg/dL)	Baseline	n	40		34		13	
		Mean (SD)	119.2 (36.58)		121.2 (32.55)		117.2 (35.99)	
		95% CI	107.5, 130.9		109.8, 132.6		95.4, 139.0	
		Median	116.0		116.0		105.0	
		Q25, Q75	94.5, 147.5		97.0, 137.0		90.0, 130.0	
		Min, Max	30, 204		62, 199		81, 197	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.



Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set

Product Use Time Period: Period 2

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
LDL Cholesterol (mg/dL)	Day 30	n	40	40	34	34	13	13
		Mean (SD)	110.8 (36.40)	-6.5 (16.99)	114.4 (29.81)	-4.8 (12.67)	114.3 (30.88)	-1.6 (9.88)
		95% CI	99.1, 122.4	-12.0, -1.1	104.0, 124.9	-9.3, -0.4	95.6, 133.0	-7.6, 4.4
		Median	107.0	-7.6	117.0	-7.7	109.0	-4.3
		Q25, Q75	89.0, 133.0	-19.9, 5.7	90.0, 136.0	-15.6, 0.7	92.0, 142.0	-9.8, 3.5
		Min, Max	24, 209	-38, 39	61, 175	-23, 24	71, 168	-15, 15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
HDL Cholesterol (mg/dL)	Baseline	n	40		34		13	
		Mean (SD)	48.3 (11.86)		52.9 (13.26)		50.9 (10.25)	
		95% CI	44.4, 52.1		48.3, 57.6		44.7, 57.2	
		Median	48.5		52.0		54.0	
		Q25, Q75	38.0, 57.0		45.0, 57.0		44.0, 56.0	
		Min, Max	28, 75		32, 90		35, 71	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
HDL Cholesterol (mg/dL)	Day 30	n	40	40	34	34	13	13
		Mean (SD)	49.2 (11.33)	3.0 (13.75)	54.0 (16.32)	2.0 (17.80)	50.6 (9.34)	0.9 (15.87)
		95% CI	45.5, 52.8	-1.4, 7.4	48.3, 59.8	-4.3, 8.2	44.9, 56.3	-8.7, 10.5
		Median	49.5	5.3	52.0	0.7	52.0	-1.8
		Q25, Q75	41.5, 56.5	-4.9, 12.3	43.0, 63.0	-8.9, 14.5	45.0, 54.0	-7.1, 8.6
		Min, Max	21, 82	-34, 27	24, 100	-45, 37	38, 74	-24, 37

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Triglycerides (mg/dL)	Baseline	n	40		34		13	
		Mean (SD)	150.8 (88.05)		126.8 (42.58)		116.2 (42.42)	
		95% CI	122.5, 179.0		111.9, 141.7		90.5, 141.8	
		Median	129.5		117.0		105.0	
		Q25, Q75	86.5, 165.5		95.0, 160.0		83.0, 120.0	
		Min, Max	57, 438		68, 219		68, 202	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Triglycerides (mg/dL)	Day 30	n	40	40	34	34	13	13
		Mean (SD)	158.0 (116.57)	5.3 (29.59)	129.4 (65.16)	2.8 (32.44)	141.1 (59.53)	23.3 (42.09)
		95% CI	120.6, 195.3	-4.2, 14.8	106.6, 152.1	-8.6, 14.2	105.1, 177.1	-2.2, 48.7
		Median	119.5	-1.4	110.5	0.6	122.0	16.2
		Q25, Q75	93.0, 182.5	-14.6, 18.5	88.0, 156.0	-13.6, 15.2	112.0, 177.0	-2.5, 43.9
		Min, Max	54, 676	-42, 72	50, 339	-71, 93	48, 276	-29, 117

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Cholesterol (mg/dL)	Baseline	n	40		34		13	
		Mean (SD)	190.6 (42.56)		192.2 (33.71)		187.7 (39.13)	
		95% CI	177.0, 204.3		180.4, 204.0		164.0, 211.4	
		Median	188.0		195.0		177.0	
		Q25, Q75	165.5, 218.0		165.0, 210.0		157.0, 205.0	
		Min, Max	90, 304		129, 273		139, 266	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Cholesterol (mg/dL)	Day 30	n	40	40	34	34	13	13
		Mean (SD)	185.2 (42.03)	-2.1 (12.32)	187.9 (36.92)	-2.2 (10.08)	188.9 (37.27)	1.2 (10.26)
		95% CI	171.7, 198.7	-6.1, 1.9	175.0, 200.8	-5.7, 1.4	166.4, 211.5	-5.0, 7.5
		Median	179.0	-2.0	192.0	-3.4	179.0	-2.8
		Q25, Q75	162.0, 204.0	-10.7, 6.2	172.0, 204.0	-10.9, 3.2	155.0, 220.0	-5.5, 7.9
		Min, Max	82, 307	-22, 28	114, 287	-22, 22	136, 255	-12, 18

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
C Reactive Protein (mg/L)	Baseline	n	39		35		12	
		BLOQ, n (%)	3 (7.7)		3 (8.6)		0	
		Geometric Mean	1.452		0.984		1.286	
		(CV%)	(201.5972)		(166.3972)		(223.9511)	
		95% CI of Geometric Mean	0.960, 2.195		0.662, 1.462		0.549, 3.014	
		Median	1.500		0.780		1.875	
		Q25, Q75	0.690, 4.940		0.540, 2.180		0.330, 3.920	
		Min, Max	0.10, 16.40		0.10, 10.00		0.22, 8.42	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
C Reactive Protein (mg/L)	Day 60	n	39	39	35	35	12	12
		BLOQ, n (%)	3 (7.7)		1 (2.9)		0	
		Geometric Mean (CV%)	1.490 (261.3672)		1.154 (132.4224)		1.327 (201.4994)	
		95% CI of Geometric Mean	0.936, 2.373		0.816, 1.630		0.591, 2.981	
		Median	1.720	-3.636	1.100	19.178	1.210	20.254
		Q25, Q75	0.490, 3.840	-35.967, 54.545	0.680, 2.200	-39.474, 85.000	0.540, 4.305	-58.477, 134.250
		Min, Max	0.10, 80.20	-75.61, 875.67	0.10, 7.47	-70.18, 940.00	0.20, 10.70	-80.89, 278.95

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Homocysteine (umol/L)	Baseline	n	39		35		12	
		Geometric Mean	9.823		9.773		11.098	
		(CV%)	(39.8089)		(25.0500)		(40.5149)	
		95% CI of	8.674, 11.124		8.979, 10.638		8.662, 14.218	
		Geometric Mean						
		Median	9.730		9.590		9.895	
		Q25, Q75	7.770, 11.070		8.240, 11.600		8.890, 16.120	
		Min, Max	5.41, 56.40		5.80, 16.60		6.09, 20.76	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Homocysteine (umol/L)	Day 60	n	39	39	35	35	12	12
		Geometric Mean (CV%)	10.095 (40.3620)		9.806 (24.9008)		10.559 (33.8594)	
		95% CI of Geometric Mean	8.900, 11.450		9.013, 10.669		8.564, 13.018	
		Median	9.440	5.744	9.670	-2.103	10.010	0.108
		Q25, Q75	8.500, 10.810	-12.595, 14.068	8.260, 11.550	-13.826, 14.795	8.240, 12.980	-13.607, 7.600
		Min, Max	5.26, 57.77	-31.98, 51.61	6.11, 16.88	-22.00, 43.29	6.42, 19.79	-52.26, 36.78

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Glucose (mg/dL)	Baseline	n	39		35		12	
		Geometric Mean (CV%)	94.1 (8.04)		93.5 (7.99)		97.3 (14.15)	
		95% CI of Geometric Mean	91.6, 96.6		91.0, 96.2		89.0, 106.5	
		Median	93.0		93.0		96.5	
		Q25, Q75	89.0, 99.0		88.0, 99.0		86.0, 107.0	
		Min, Max	83, 118		83, 116		81, 132	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Glucose (mg/dL)	Day 60	n	39	39	35	35	12	12
		Geometric Mean (CV%)	93.9 (10.48)		91.1 (8.78)		100.2 (21.21)	
		95% CI of Geometric Mean	90.7, 97.2		88.3, 93.9		87.6, 114.5	
		Median	94.0	1.2	91.0	-2.9	95.5	3.2
		Q25, Q75	89.0, 100.0	-4.8, 5.5	86.0, 96.0	-8.0, 2.1	89.0, 109.5	0.5, 4.8
		Min, Max	74, 124	-19, 17	76, 114	-20, 20	76, 173	-16, 31

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
LDL Cholesterol (mg/dL)	Baseline	n	39		35		12	
		Mean (SD)	117.8 (37.28)		122.2 (32.64)		119.6 (30.59)	
		95% CI	105.7, 130.0		111.0, 133.5		100.1, 139.1	
		Median	114.0		117.0		119.5	
		Q25, Q75	90.0, 148.0		97.0, 141.0		91.0, 147.5	
		Min, Max	30, 204		62, 199		81, 164	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
LDL Cholesterol (mg/dL)	Day 60	n	39	39	35	35	12	12
		Mean (SD)	107.4 (32.29)	-6.8 (16.14)	112.3 (30.59)	-7.5 (11.86)	116.4 (25.23)	-1.5 (11.64)
		95% CI	96.9, 118.0	-12.1, -1.5	101.7, 122.8	-11.6, -3.4	100.3, 132.5	-8.9, 6.0
		Median	102.0	-8.2	111.0	-7.5	122.0	-0.5
		Q25, Q75	83.0, 133.0	-20.2, 4.4	89.0, 135.0	-12.5, -1.6	104.5, 134.0	-9.6, 4.8
		Min, Max	35, 183	-40, 27	61, 180	-47, 17	66, 150	-20, 20

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
HDL Cholesterol (mg/dL)	Baseline	n	39		35		12	
		Mean (SD)	46.5 (10.50)		54.1 (14.80)		51.2 (8.78)	
		95% CI	43.1, 50.0		49.0, 59.2		45.5, 56.8	
		Median	47.0		52.0		54.5	
		Q25, Q75	38.0, 53.0		45.0, 58.0		44.0, 56.5	
		Min, Max	28, 72		32, 94		35, 64	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
HDL Cholesterol (mg/dL)	Day 60	n	39	39	35	35	12	12
		Mean (SD)	48.2 (11.70)	4.1 (12.17)	54.5 (16.37)	0.5 (11.30)	52.7 (8.00)	4.0 (13.70)
		95% CI	44.4, 52.0	0.1, 8.1	48.8, 60.1	-3.4, 4.4	47.5, 57.8	-4.8, 12.7
		Median	48.0	3.1	52.0	-2.1	54.0	1.8
		Q25, Q75	41.0, 54.0	-3.1, 10.4	43.0, 61.0	-7.7, 8.7	49.5, 57.5	-8.0, 11.8
		Min, Max	30, 86	-21, 38	29, 94	-23, 29	33, 63	-13, 29

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.



Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set

Product Use Time Period: Period 3

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Triglycerides (mg/dL)	Baseline	n	39		35		12	
		Mean (SD)	152.4 (87.00)		125.8 (42.36)		116.5 (49.00)	
		95% CI	124.1, 180.6		111.2, 140.4		85.3, 147.7	
		Median	130.0		116.0		101.0	
		Q25, Q75	87.0, 158.0		94.0, 160.0		82.5, 119.5	
		Min, Max	64, 438		68, 219		68, 227	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Triglycerides (mg/dL)	Day 60	n	39	39	35	35	12	12
		Mean (SD)	151.1 (78.78)	3.1 (26.13)	142.9 (55.92)	15.9 (29.27)	130.7 (49.59)	14.7 (31.72)
		95% CI	125.5, 176.7	-5.5, 11.6	123.7, 162.2	5.8, 26.0	99.1, 162.2	-5.5, 34.9
		Median	128.0	-3.8	128.0	10.3	123.0	6.6
		Q25, Q75	101.0, 169.0	-15.7, 17.6	108.0, 166.0	1.9, 33.1	103.5, 167.5	-3.6, 31.0
		Min, Max	52, 384	-35, 75	71, 332	-53, 87	43, 217	-37, 84

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Cholesterol (mg/dL)	Baseline	n	39		35		12	
		Mean (SD)	187.5 (42.91)		194.1 (35.02)		190.8 (37.81)	
		95% CI	173.5, 201.4		182.0, 206.2		166.8, 214.9	
		Median	181.0		196.0		184.0	
		Q25, Q75	164.0, 217.0		165.0, 218.0		158.5, 222.5	
		Min, Max	90, 304		129, 273		139, 251	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Cholesterol (mg/dL)	Day 60	n	39	39	35	35	12	12
		Mean (SD)	179.8 (39.57)	-3.0 (12.84)	187.8 (33.35)	-2.7 (9.47)	189.2 (33.86)	-0.2 (10.52)
		95% CI	167.0, 192.7	-7.2, 1.2	176.3, 199.3	-6.1, 0.6	167.6, 210.7	-7.0, 6.5
		Median	176.0	-3.2	188.0	-1.9	193.0	-0.3
		Q25, Q75	149.0, 208.0	-14.6, 7.5	162.0, 211.0	-7.1, 2.9	171.0, 217.0	-6.9, 5.7
		Min, Max	101, 294	-26, 25	123, 258	-27, 14	119, 231	-21, 16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
C Reactive Protein (mg/L)	Baseline	n	47		32		9	
		BLOQ, n (%)	3 (6.4)		3 (9.4)		0	
		Geometric Mean	1.322		1.028		0.855	
		(CV%)	(182.3235)		(174.8224)		(204.2912)	
		95% CI of Geometric Mean	0.926, 1.887		0.671, 1.576		0.319, 2.290	
		Median	1.380		0.800		0.660	
		Q25, Q75	0.690, 2.910		0.620, 2.190		0.280, 2.330	
		Min, Max	0.10, 16.40		0.10, 10.00		0.22, 8.42	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
C Reactive Protein (mg/L)	Day 90	n	47	47	32	32	9	9
		BLOQ, n (%)	4 (8.5)		2 (6.3)		1 (11.1)	
		Geometric Mean	1.370		1.298		0.937	
		(CV%)	(211.3840)		(160.2374)		(227.9212)	
		95% CI of Geometric Mean	0.934, 2.009		0.864, 1.950		0.331, 2.648	
		Median	1.400	-5.072	1.410	2.564	0.700	56.522
		Q25, Q75	0.580, 3.790	-36.458, 40.404	0.660, 3.000	-23.714, 82.122	0.360, 2.800	-46.437, 95.279
		Min, Max	0.10, 16.40	-75.61, 2342.31	0.10, 9.78	-65.71, 2956.25	0.10, 4.55	-71.54, 324.24

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Homocysteine (umol/L)	Baseline	n	47		32		9	
		Geometric Mean	9.927		9.671		10.783	
		(CV%)	(39.7166)		(25.7355)		(40.0857)	
		95% CI of	8.871, 11.108		8.826, 10.596		8.014, 14.509	
		Geometric Mean						
		Median	9.730		9.515		9.790	
		Q25, Q75	7.820, 11.070		8.165, 11.540		9.250, 14.760	
		Min, Max	5.41, 56.40		5.80, 16.60		6.09, 19.21	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Homocysteine (umol/L)	Day 90	n	47	47	32	32	9	9
		Geometric Mean (CV%)	10.848 (42.8732)		10.457 (24.2235)		11.031 (45.3586)	
		95% CI of Geometric Mean	9.615, 12.239		9.593, 11.397		7.910, 15.383	
		Median	10.340	10.777	10.765	9.614	13.090	1.220
		Q25, Q75	8.790, 12.540	-6.892, 25.169	8.725, 12.880	-6.066, 22.029	6.780, 14.940	-5.882, 9.195
		Min, Max	5.66, 64.50	-19.71, 57.64	6.36, 15.39	-22.71, 83.89	6.09, 18.08	-26.70, 45.86

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.



Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set

Product Use Time Period: Period 4

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Glucose (mg/dL)	Baseline	n	47		32		9	
		Geometric Mean (CV%)	93.3 (7.73)		94.0 (8.14)		94.0 (11.59)	
		95% CI of Geometric Mean	91.2, 95.5		91.3, 96.9		86.0, 102.8	
		Median	92.0		94.0		96.0	
		Q25, Q75	88.0, 98.0		88.0, 99.5		86.0, 98.0	
		Min, Max	83, 118		83, 116		81, 112	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Glucose (mg/dL)	Day 91/Discharge Ambulatory	n	47	47	32	32	9	9
		Geometric Mean (CV%)	94.2 (9.21)		92.3 (8.04)		95.9 (9.76)	
		95% CI of Geometric Mean	91.6, 96.8		89.6, 95.1		89.0, 103.4	
		Median	93.0	0.0	94.0	-3.1	97.0	-1.2
		Q25, Q75	88.0, 100.0	-4.7, 7.5	88.5, 95.5	-8.0, 6.5	89.0, 105.0	-3.6, 6.3
		Min, Max	81, 127	-16, 33	77, 113	-34, 24	84, 107	-6, 20

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
LDL Cholesterol (mg/dL)	Baseline	n	47		32		9	
		Mean (SD)	114.9 (36.21)		122.7 (33.65)		117.7 (29.72)	
		95% CI	104.3, 125.6		110.5, 134.9		94.8, 140.6	
		Median	113.0		116.0		114.0	
		Q25, Q75	87.0, 144.0		98.0, 145.5		92.0, 130.0	
		Min, Max	30, 204		62, 199		83, 164	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.



Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set

Product Use Time Period: Period 4

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
LDL Cholesterol (mg/dL)	Day 90	n	47	47	32	32	9	9
		Mean (SD)	108.4 (35.46)	-3.9 (18.81)	118.1 (33.51)	-3.1 (13.53)	115.4 (35.86)	-2.8 (11.60)
		95% CI	97.9, 118.8	-9.5, 1.6	106.0, 130.2	-8.0, 1.8	87.8, 143.1	-11.7, 6.2
		Median	107.0	-5.9	116.0	-3.5	105.0	-7.9
		Q25, Q75	82.0, 127.0	-17.6, 8.5	92.0, 137.0	-11.8, 0.5	90.0, 142.0	-12.0, 7.9
		Min, Max	43, 217	-33, 43	62, 200	-24, 39	73, 177	-15, 14

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
HDL Cholesterol (mg/dL)	Baseline	n	47		32		9	
		Mean (SD)	48.7 (11.48)		55.0 (15.15)		52.8 (8.41)	
		95% CI	45.3, 52.1		49.5, 60.5		46.3, 59.3	
		Median	48.0		54.0		55.0	
		Q25, Q75	39.0, 57.0		46.0, 62.0		54.0, 56.0	
		Min, Max	28, 75		32, 94		35, 64	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
HDL Cholesterol (mg/dL)	Day 90	n	47	47	32	32	9	9
		Mean (SD)	52.1 (12.00)	8.1 (13.51)	56.3 (17.11)	3.0 (16.13)	54.1 (8.26)	3.1 (9.99)
		95% CI	48.6, 55.7	4.1, 12.1	50.1, 62.6	-2.9, 8.8	47.7, 60.5	-4.7, 10.8
		Median	51.0	5.7	54.5	1.0	54.0	2.9
		Q25, Q75	45.0, 61.0	-2.9, 20.0	44.5, 63.5	-7.0, 13.9	53.0, 58.0	-1.9, 3.6
		Min, Max	30, 88	-13, 49	27, 107	-27, 41	36, 63	-11, 20

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Triglycerides (mg/dL)	Baseline	n	47		32		9	
		Mean (SD)	145.7 (82.02)		121.6 (41.82)		106.6 (47.70)	
		95% CI	121.6, 169.9		106.5, 136.8		69.8, 143.3	
		Median	128.0		106.0		95.0	
		Q25, Q75	88.0, 156.0		93.0, 147.5		82.0, 107.0	
		Min, Max	64, 438		68, 219		68, 227	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Triglycerides (mg/dL)	Day 91/Discharge Ambulatory	n	47	47	32	32	9	9
		Mean (SD)	146.3 (75.34)	4.4 (25.78)	125.7 (45.09)	4.4 (21.59)	102.1 (37.94)	-0.1 (34.12)
		95% CI	124.1, 168.4	-3.2, 12.0	109.4, 142.0	-3.5, 12.2	72.9, 131.3	-26.4, 26.2
		Median	124.0	0.9	115.0	2.7	103.0	-9.2
		Q25, Q75	93.0, 191.0	-15.1, 20.8	85.5, 163.5	-10.3, 21.2	74.0, 115.0	-13.2, 6.3
		Min, Max	55, 397	-51, 54	58, 217	-46, 52	48, 163	-41, 77

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Cholesterol (mg/dL)	Baseline	n	47		32		9	
		Mean (SD)	185.7 (41.87)		195.1 (35.40)		188.0 (38.65)	
		95% CI	173.4, 198.0		182.3, 207.9		158.2, 217.8	
		Median	181.0		195.0		177.0	
		Q25, Q75	162.0, 216.0		166.5, 220.0		164.0, 205.0	
		Min, Max	90, 304		129, 273		139, 251	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Cholesterol (mg/dL)	Day 91/Discharge Ambulatory	n	47	47	32	32	9	9
		Mean (SD)	182.8 (39.92)	-0.7 (11.76)	195.0 (37.02)	0.2 (9.16)	185.4 (46.60)	-2.0 (9.36)
		95% CI	171.0, 194.6	-4.2, 2.8	181.6, 208.4	-3.2, 3.5	149.6, 221.3	-9.2, 5.2
		Median	180.0	-0.9	190.5	1.1	166.0	-6.2
		Q25, Q75	150.0, 207.0	-9.1, 6.9	168.5, 222.0	-7.0, 4.1	159.0, 221.0	-8.1, 3.4
		Min, Max	111, 310	-22, 26	120, 278	-16, 31	126, 258	-13, 16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Apo A1 (mg/dL)	Baseline	n	47		32		9	
		Mean (SD)	140.2 (20.04)		147.8 (27.06)		141.0 (16.41)	
		95% CI	134.3, 146.1		138.0, 157.6		128.3, 153.7	
		Median	139.0		145.0		142.0	
		Q25, Q75	123.0, 155.0		132.5, 165.5		133.0, 153.0	
		Min, Max	102, 183		96, 214		107, 161	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Apo A1 (mg/dL)	Day 90	n	47	47	32	32	9	9
		Mean (SD)	148.7 (23.11)	6.5 (11.30)	152.6 (29.19)	3.9 (12.57)	146.0 (21.13)	3.5 (8.72)
		95% CI	141.9, 155.6	3.1, 9.9	142.0, 163.2	-0.7, 8.5	129.7, 162.3	-3.3, 10.2
		Median	148.0	8.1	148.5	1.5	146.0	2.0
		Q25, Q75	135.0, 165.0	-1.6, 13.8	128.0, 168.5	-5.3, 12.2	143.0, 158.0	-2.8, 9.8
		Min, Max	105, 208	-17, 32	105, 221	-19, 28	104, 174	-11, 18

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Apo B (mg/dL)	Baseline	n	47		32		9	
		Mean (SD)	87.7 (27.79)		90.8 (21.49)		82.4 (17.33)	
		95% CI	79.5, 95.9		83.0, 98.6		69.1, 95.8	
		Median	87.0		87.5		80.0	
		Q25, Q75	66.0, 106.0		78.5, 101.5		67.0, 95.0	
		Min, Max	18, 168		53, 150		64, 107	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.1 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Apo B (mg/dL)	Day 90	n	47	47	32	32	9	9
		Mean (SD)	84.8 (28.44)	-2.5 (15.12)	88.8 (23.35)	-2.2 (11.80)	82.6 (25.02)	-1.1 (12.55)
		95% CI	76.4, 93.2	-7.0, 2.0	80.3, 97.3	-6.5, 2.1	63.3, 101.8	-10.8, 8.6
		Median	85.0	-1.6	89.5	-2.0	74.0	-6.3
		Q25, Q75	65.0, 101.0	-12.5, 6.1	71.0, 102.0	-8.3, 3.7	64.0, 99.0	-7.5, 4.2
		Min, Max	18, 180	-30, 37	44, 154	-24, 23	56, 130	-13, 26

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
C Reactive Protein (mg/L)	Baseline	n	80		41		39	
		BLOQ, n (%)	4 (5.0)		3 (7.3)		2 (5.1)	
		Geometric Mean	1.329		1.146		1.273	
		(CV%)	(176.5286)		(203.8437)		(257.2213)	
		95% CI of Geometric Mean	1.019, 1.732		0.764, 1.717		0.802, 2.022	
		Median	1.310		0.820		1.010	
		Q25, Q75	0.665, 2.875		0.600, 2.200		0.380, 5.380	
		Min, Max	0.10, 34.20		0.10, 48.60		0.10, 15.80	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
C Reactive Protein (mg/L)	Day 30	n	80	80	41	41	39	39
		BLOQ, n (%)	4 (5.0)		2 (4.9)		3 (7.7)	
		Geometric Mean	1.316		1.483		1.029	
		(CV%)	(166.1068)		(170.2601)		(213.4293)	
		95% CI of Geometric Mean	1.018, 1.701		1.026, 2.144		0.673, 1.574	
		Median	1.300	0.000	1.180	9.959	0.650	-8.163
		Q25, Q75	0.610, 2.900	-33.965, 39.343	0.800, 2.750	-15.854, 86.667	0.410, 3.520	-47.183, 10.847
		Min, Max	0.10, 25.50	-97.87, 434.09	0.10, 31.60	-96.91, 878.33	0.10, 13.30	-81.59, 1290.00

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
C Reactive Protein (mg/L)	Day 60	n	80	80	41	41	39	39
		BLOQ, n (%)	5 (6.3)		1 (2.4)		3 (7.7)	
		Geometric Mean	1.404		1.269		1.227	
		(CV%)	(200.9163)		(130.6941)		(234.6399)	
		95% CI of Geometric Mean	1.057, 1.863		0.925, 1.739		0.787, 1.912	
		Median	1.370	0.926	1.110	12.676	0.980	0.000
		Q25, Q75	0.640, 3.450	-37.941, 68.973	0.760, 2.270	-35.246, 72.868	0.460, 4.770	-53.465, 66.276
		Min, Max	0.10, 80.20	-98.80, 2483.33	0.10, 7.47	-95.33, 940.00	0.10, 10.70	-91.45, 2630.00

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
C Reactive Protein (mg/L)	Day 90	n	80	80	41	41	39	39
		BLOQ, n (%)	6 (7.5)		2 (4.9)		1 (2.6)	
		Geometric Mean	1.378		1.459		1.353	
		(CV%)	(192.2552)		(146.4486)		(218.7855)	
		95% CI of Geometric Mean	1.044, 1.817		1.041, 2.047		0.880, 2.079	
		Median	1.395	0.000	1.690	5.128	0.980	0.000
		Q25, Q75	0.620, 3.460	-37.148, 64.224	0.800, 3.080	-24.528, 93.750	0.450, 4.770	-41.544, 64.789
		Min, Max	0.10, 23.00	-98.25, 2342.31	0.10, 9.78	-89.71, 2956.25	0.10, 14.70	-75.21, 2586.67

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Homocysteine (umol/L)	Baseline	n	80		41		39	
		Geometric Mean (CV%)	9.612 (35.8429)		9.451 (27.8952)		9.670 (28.3188)	
		95% CI of Geometric Mean	8.896, 10.386		8.668, 10.304		8.837, 10.582	
		Median	9.290		9.560		9.030	
		Q25, Q75	7.775, 11.115		8.090, 11.480		8.280, 11.070	
		Min, Max	5.04, 56.40		5.38, 16.60		6.09, 20.76	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Homocysteine (umol/L)	Day 30	n	80	80	41	41	39	39
		Geometric Mean (CV%)	9.562 (35.1940)		9.282 (29.0560)		9.963 (31.5930)	
		95% CI of Geometric Mean	8.861, 10.318		8.484, 10.155		9.015, 11.011	
		Median	9.630	-0.195	8.930	-2.955	9.390	0.000
		Q25, Q75	7.810, 11.125	-7.849, 7.065	7.970, 12.150	-14.865, 9.911	8.050, 11.980	-6.787, 12.737
		Min, Max	5.10, 42.29	-27.84, 46.86	4.89, 15.55	-27.23, 45.63	5.86, 19.87	-36.45, 68.90

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Homocysteine (umol/L)	Day 60	n	80	80	41	41	39	39
		Geometric Mean (CV%)	9.864 (38.1747)		9.374 (27.1170)		9.690 (25.2128)	
		95% CI of Geometric Mean	9.086, 10.708		8.618, 10.197		8.940, 10.502	
		Median	9.405	4.612	9.490	-4.304	9.110	0.000
		Q25, Q75	8.140, 10.720	-10.578, 13.514	8.170, 11.170	-13.826, 12.919	8.200, 11.540	-3.833, 8.400
		Min, Max	5.26, 57.77	-31.98, 72.80	5.59, 16.88	-22.00, 43.29	6.42, 19.79	-52.26, 54.98

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Homocysteine (umol/L)	Day 90	n	80	80	41	41	39	39
		Geometric Mean (CV%)	10.350 (39.7524)		10.059 (25.9913)		10.321 (31.7373)	
		95% CI of Geometric Mean	9.504, 11.271		9.279, 10.905		9.334, 11.412	
		Median	10.160	7.174	10.280	4.294	10.170	5.258
		Q25, Q75	8.345, 12.510	-4.053, 20.912	8.300, 12.630	-8.884, 20.740	8.280, 13.090	-0.530, 20.054
		Min, Max	4.37, 64.50	-25.95, 57.64	5.79, 15.55	-22.71, 83.89	6.09, 20.65	-31.61, 67.78

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Glucose (mg/dL)	Baseline	n	80		41		39	
		Geometric Mean (CV%)	93.9 (7.37)		93.3 (8.01)		95.0 (10.49)	
		95% CI of Geometric Mean	92.3, 95.5		90.9, 95.7		91.8, 98.3	
		Median	93.0		93.0		94.0	
		Q25, Q75	89.5, 98.5		88.0, 98.0		88.0, 101.0	
		Min, Max	83, 118		83, 116		81, 132	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Glucose (mg/dL)	Day 6/Discharge Confinement	n	80	80	40	40	35	35
		Missing, n(%)	0	0	1 (2.4)	1 (2.4)	4 (10.3)	4 (10.3)
		Geometric Mean (CV%)	89.1 (9.07)		84.9 (6.10)		90.2 (9.31)	
		95% CI of Geometric Mean	87.2, 90.9		83.2, 86.6		87.3, 93.2	
		Median	88.5	-4.6	85.0	-9.4	90.0	-3.6
		Q25, Q75	84.0, 93.0	-10.3, -1.1	82.0, 87.5	-13.5, -5.5	85.0, 95.0	-7.5, 1.1
		Min, Max	75, 139	-23, 53	74, 97	-21, 8	72, 115	-25, 10

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Glucose (mg/dL)	Day 30	n	80	80	41	41	39	39
		Geometric Mean (CV%)	93.4 (7.87)		91.8 (6.77)		94.4 (10.84)	
		95% CI of Geometric Mean	91.8, 95.1		89.8, 93.9		91.1, 97.8	
		Median	93.0	0.0	92.0	-1.2	93.0	0.0
		Q25, Q75	89.0, 98.0	-4.8, 2.3	88.0, 97.0	-4.7, 3.2	88.0, 100.0	-4.5, 3.3
		Min, Max	77, 120	-16, 19	78, 103	-16, 10	83, 147	-13, 11

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Glucose (mg/dL)	Day 60	n	80	80	41	41	39	39
		Geometric Mean (CV%)	92.8 (9.17)		90.7 (8.54)		96.6 (13.46)	
		95% CI of Geometric Mean	90.8, 94.7		88.2, 93.2		92.4, 100.9	
		Median	93.0	-0.5	91.0	-2.9	94.0	2.1
		Q25, Q75	89.0, 98.0	-5.6, 4.7	86.0, 94.0	-7.2, 1.9	90.0, 102.0	-4.1, 6.1
		Min, Max	72, 124	-19, 17	76, 114	-20, 20	76, 173	-16, 31

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Glucose (mg/dL)	Day 91/Discharge n Ambulatory		80	80	41	41	39	39
		Geometric Mean (CV%)	93.4 (8.29)		91.4 (7.84)		96.5 (12.24)	
		95% CI of Geometric Mean	91.7, 95.2		89.1, 93.7		92.7, 100.4	
		Median	93.0	-1.1	92.0	-3.8	95.0	0.0
		Q25, Q75	88.0, 98.5	-4.9, 4.5	87.0, 94.0	-7.4, 3.5	91.0, 102.0	-3.7, 7.3
		Min, Max	81, 127	-17, 33	77, 113	-34, 24	79, 168	-10, 27

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
LDL Cholesterol (mg/dL)	Baseline	n	80		41		39	
		Mean (SD)	116.8 (35.33)		120.8 (33.00)		124.8 (35.74)	
		95% CI	108.9, 124.7		110.4, 131.3		113.2, 136.4	
		Median	113.5		115.0		117.0	
		Q25, Q75	90.5, 147.0		97.0, 137.0		92.0, 160.0	
		Min, Max	30, 204		62, 199		71, 197	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
LDL Cholesterol (mg/dL)	Day 30	n	80	80	41	41	39	39
		Mean (SD)	107.2 (34.75)	-7.5 (16.76)	112.0 (29.85)	-6.4 (13.00)	117.2 (32.71)	-4.4 (16.40)
		95% CI	99.4, 114.9	-11.3, -3.7	102.6, 121.5	-10.5, -2.2	106.6, 127.9	-9.7, 1.0
		Median	105.5	-7.5	110.0	-8.7	114.0	-4.3
		Q25, Q75	84.0, 130.5	-19.2, 1.6	86.0, 133.0	-15.6, 0.0	92.0, 140.0	-12.3, 3.1
		Min, Max	24, 209	-41, 39	61, 175	-32, 24	55, 185	-65, 51

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
LDL Cholesterol (mg/dL)	Day 60	n	80	80	41	41	39	39
		Mean (SD)	103.6 (30.74)	-9.4 (17.31)	109.3 (30.21)	-8.8 (12.40)	119.7 (34.79)	-2.7 (16.53)
		95% CI	96.7, 110.5	-13.3, -5.5	99.7, 118.9	-12.8, -4.8	108.4, 131.0	-8.1, 2.7
		Median	101.5	-11.0	110.0	-7.5	117.0	0.0
		Q25, Q75	83.5, 124.5	-22.2, 2.1	83.0, 129.0	-13.1, -2.1	94.0, 140.0	-10.6, 5.4
		Min, Max	35, 183	-53, 30	61, 180	-47, 17	52, 200	-59, 43

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
LDL Cholesterol (mg/dL)	Day 90	n	80	80	41	41	39	39
		Mean (SD)	108.7 (33.43)	-5.0 (18.94)	115.6 (32.78)	-3.7 (12.96)	121.9 (38.82)	-0.8 (22.91)
		95% CI	101.2, 116.2	-9.2, -0.7	105.2, 126.0	-7.8, 0.5	109.3, 134.6	-8.3, 6.7
		Median	111.0	-5.7	110.0	-3.3	123.0	0.0
		Q25, Q75	83.0, 128.5	-20.0, 7.0	93.0, 132.0	-11.3, 0.5	92.0, 152.0	-12.0, 2.5
		Min, Max	43, 217	-53, 43	62, 200	-28, 39	58, 209	-66, 105

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
HDL Cholesterol (mg/dL)	Baseline	n	80		41		39	
		Mean (SD)	51.7 (13.35)		53.3 (14.04)		51.4 (10.00)	
		95% CI	48.7, 54.7		48.8, 57.8		48.1, 54.7	
		Median	51.0		52.0		51.0	
		Q25, Q75	42.0, 59.0		45.0, 57.0		45.0, 57.0	
		Min, Max	28, 89		32, 94		35, 80	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
HDL Cholesterol (mg/dL)	Day 30	n	80	80	41	41	39	39
		Mean (SD)	52.6 (14.17)	2.6 (16.46)	54.4 (16.76)	2.1 (16.78)	51.2 (11.94)	0.8 (20.62)
		95% CI	49.4, 55.8	-1.1, 6.3	49.1, 59.8	-3.3, 7.4	47.3, 55.1	-6.0, 7.5
		Median	51.5	0.7	52.0	0.0	50.0	0.0
		Q25, Q75	42.5, 60.0	-6.8, 10.9	43.0, 63.0	-8.5, 10.5	43.0, 56.0	-11.1, 2.6
		Min, Max	21, 88	-38, 57	24, 100	-45, 37	36, 90	-40, 82

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
HDL Cholesterol (mg/dL)	Day 60	n	80	80	41	41	39	39
		Mean (SD)	53.5 (15.17)	4.2 (16.52)	53.5 (16.14)	0.1 (13.24)	50.0 (8.82)	-1.3 (15.94)
		95% CI	50.1, 57.0	0.5, 7.9	48.3, 58.6	-4.1, 4.3	47.1, 52.9	-6.5, 3.9
		Median	51.0	2.1	51.0	-2.4	49.0	-2.0
		Q25, Q75	42.5, 61.0	-6.7, 11.2	43.0, 59.0	-8.8, 7.4	44.0, 57.0	-12.9, 5.0
		Min, Max	29, 96	-26, 69	29, 94	-23, 42	33, 70	-38, 58

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
HDL Cholesterol (mg/dL)	Day 90	n	80	80	41	41	39	39
		Mean (SD)	56.6 (16.97)	9.8 (18.58)	54.1 (16.43)	1.8 (16.37)	52.0 (11.32)	1.7 (14.99)
		95% CI	52.7, 60.4	5.6, 14.0	48.9, 59.4	-3.4, 7.0	48.3, 55.7	-3.2, 6.6
		Median	53.0	5.3	53.0	-2.1	51.0	0.0
		Q25, Q75	45.0, 64.5	-2.8, 19.8	41.0, 63.0	-7.7, 12.5	45.0, 62.0	-5.0, 3.6
		Min, Max	28, 117	-18, 92	27, 107	-27, 41	36, 83	-25, 66

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Triglycerides (mg/dL)	Baseline	n	80		41		39	
		Mean (SD)	135.8 (69.59)		129.6 (45.39)		124.6 (43.89)	
		95% CI	120.3, 151.3		115.3, 144.0		110.4, 138.9	
		Median	121.0		118.0		114.0	
		Q25, Q75	89.0, 156.0		94.0, 162.0		86.0, 157.0	
		Min, Max	54, 438		68, 248		68, 238	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Triglycerides (mg/dL)	Day 6/Discharge Confinement	n	80	80	40	40	35	35
		Missing, n(%)	0	0	1 (2.4)	1 (2.4)	4 (10.3)	4 (10.3)
		Mean (SD)	124.8 (71.83)	-6.6 (24.90)	115.2 (50.44)	-10.8 (19.44)	124.6 (57.53)	1.6 (35.45)
		95% CI	108.7, 140.8	-12.1, -1.0	99.0, 131.4	-17.1, -4.6	104.8, 144.4	-10.7, 13.8
		Median	95.0	-8.1	97.5	-12.5	120.0	-11.9
		Q25, Q75	80.0, 146.5	-22.3, 4.6	76.0, 156.5	-21.0, 1.9	78.0, 157.0	-25.3, 27.3
		Min, Max	60, 430	-54, 77	60, 232	-56, 38	47, 302	-54, 88

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Triglycerides (mg/dL)	Day 30	n	80	80	41	41	39	39
		Mean (SD)	140.9 (92.44)	4.3 (29.42)	130.8 (72.40)	0.4 (32.10)	142.5 (59.11)	15.5 (34.43)
		95% CI	120.3, 161.5	-2.3, 10.9	107.9, 153.7	-9.8, 10.6	123.3, 161.7	4.3, 26.8
		Median	118.5	-2.7	109.0	-2.1	134.0	3.5
		Q25, Q75	92.0, 159.5	-17.5, 24.9	85.0, 156.0	-17.6, 13.3	101.0, 177.0	-5.1, 27.4
		Min, Max	47, 676	-55, 72	50, 364	-71, 93	48, 302	-30, 117

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Triglycerides (mg/dL)	Day 60	n	80	80	41	41	39	39
		Mean (SD)	139.7 (74.91)	5.3 (29.46)	145.0 (60.43)	13.4 (28.24)	135.3 (52.60)	8.9 (22.27)
		95% CI	123.0, 156.4	-1.3, 11.9	125.9, 164.1	4.5, 22.4	118.2, 152.4	1.6, 16.2
		Median	120.0	2.9	128.0	8.5	131.0	5.6
		Q25, Q75	93.0, 164.5	-16.4, 19.7	108.0, 168.0	-4.6, 24.0	100.0, 160.0	-3.9, 23.8
		Min, Max	49, 432	-60, 95	71, 332	-53, 87	43, 302	-37, 84

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Triglycerides (mg/dL)	Day 91/Discharge n Ambulatory		80	80	41	41	39	39
		Mean (SD)	134.9 (70.51)	2.4 (29.87)	134.7 (64.98)	3.8 (26.81)	131.5 (62.69)	5.0 (30.79)
		95% CI	119.1, 150.6	-4.3, 9.1	114.2, 155.3	-4.7, 12.3	111.1, 151.9	-5.0, 15.0
		Median	116.0	-2.3	115.0	0.9	122.0	0.0
		Q25, Q75	85.5, 163.5	-18.3, 16.8	91.0, 167.0	-10.9, 20.7	91.0, 155.0	-11.4, 14.5
		Min, Max	55, 397	-60, 93	58, 369	-53, 87	48, 320	-41, 130

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Cholesterol (mg/dL)	Baseline	n	80		41		39	
		Mean (SD)	189.9 (39.47)		192.9 (36.05)		193.8 (37.37)	
		95% CI	181.1, 198.8		181.5, 204.3		181.6, 206.0	
		Median	189.0		194.0		188.0	
		Q25, Q75	164.5, 215.5		164.0, 217.0		161.0, 230.0	
		Min, Max	90, 304		129, 273		139, 266	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Cholesterol (mg/dL)	Day 6/Discharge Confinement	n	80	80	40	40	35	35
		Missing, n(%)	0	0	1 (2.4)	1 (2.4)	4 (10.3)	4 (10.3)
		Mean (SD)	176.9 (35.00)	-6.3 (9.43)	174.0 (33.50)	-9.8 (8.16)	187.5 (39.94)	-4.3 (10.25)
		95% CI	169.1, 184.8	-8.4, -4.1	163.2, 184.7	-12.4, -7.1	173.7, 201.2	-7.9, -0.8
		Median	179.0	-6.4	177.5	-10.4	184.0	-3.3
		Q25, Q75	149.0, 200.5	-12.0, -0.7	148.0, 197.0	-15.5, -4.2	152.0, 218.0	-11.0, 3.0
		Min, Max	77, 278	-30, 21	109, 249	-23, 15	110, 274	-31, 15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Cholesterol (mg/dL)	Day 30	n	80	80	41	41	39	39
		Mean (SD)	182.1 (40.84)	-3.6 (12.92)	186.4 (37.41)	-3.1 (10.28)	190.6 (35.27)	-1.1 (9.79)
		95% CI	173.0, 191.3	-6.5, -0.6	174.5, 198.2	-6.4, 0.2	179.1, 202.1	-4.3, 2.1
		Median	179.0	-2.2	185.0	-3.7	192.0	-2.8
		Q25, Q75	156.5, 202.0	-11.9, 3.7	164.0, 201.0	-10.9, 2.6	157.0, 222.0	-7.1, 4.8
		Min, Max	82, 307	-44, 29	114, 287	-24, 22	121, 262	-18, 18

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Cholesterol (mg/dL)	Day 60	n	80	80	41	41	39	39
		Mean (SD)	179.2 (35.65)	-4.6 (12.41)	184.5 (34.25)	-3.8 (10.24)	190.1 (38.63)	-1.7 (10.56)
		95% CI	171.2, 187.2	-7.4, -1.8	173.7, 195.4	-7.1, -0.5	177.5, 202.6	-5.2, 1.8
		Median	177.5	-5.5	184.0	-2.1	196.0	-1.1
		Q25, Q75	156.0, 200.5	-15.5, 6.3	162.0, 207.0	-9.0, 2.6	160.0, 221.0	-8.7, 3.9
		Min, Max	101, 294	-31, 25	116, 258	-27, 14	115, 275	-21, 24

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Cholesterol (mg/dL)	Day 91/Discharge n Ambulatory		80	80	41	41	39	39
		Mean (SD)	184.8 (37.52)	-1.7 (12.52)	191.6 (39.61)	-0.6 (9.64)	194.8 (44.73)	0.3 (11.20)
		95% CI	176.4, 193.2	-4.6, 1.1	179.0, 204.1	-3.6, 2.5	180.3, 209.4	-3.3, 4.0
		Median	185.0	-2.4	180.0	0.0	190.0	0.0
		Q25, Q75	154.5, 207.5	-9.9, 6.8	168.0, 214.0	-7.0, 3.9	159.0, 231.0	-6.2, 3.9
		Min, Max	111, 310	-31, 26	120, 292	-20, 31	122, 305	-21, 43

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Apo A1 (mg/dL)	Baseline	n	80		41		39	
		Mean (SD)	142.8 (20.45)		144.2 (25.67)		143.6 (18.44)	
		95% CI	138.2, 147.4		136.1, 152.4		137.6, 149.6	
		Median	140.5		142.0		141.0	
		Q25, Q75	128.0, 159.5		130.0, 158.0		133.0, 155.0	
		Min, Max	100, 183		96, 214		107, 212	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Apo A1 (mg/dL) Day 90		n	80	80	41	41	39	39
		Mean (SD)	154.1 (26.78)	8.4 (14.85)	148.7 (28.04)	3.5 (11.32)	142.4 (23.62)	-0.5 (13.24)
		95% CI	148.1, 160.1	5.1, 11.8	139.8, 157.6	-0.1, 7.2	134.7, 150.1	-4.8, 3.8
		Median	151.0	6.5	145.0	0.9	140.0	0.0
		Q25, Q75	136.0, 175.0	0.0, 15.2	129.0, 165.0	-2.6, 9.5	123.0, 158.0	-9.2, 2.0
		Min, Max	105, 238	-17, 81	105, 221	-19, 28	104, 210	-30, 33

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Apo B (mg/dL)	Baseline	n	80		41		39	
		Mean (SD)	88.3 (26.31)		90.6 (21.98)		89.5 (25.17)	
		95% CI	82.4, 94.2		83.6, 97.6		81.3, 97.7	
		Median	87.0		88.0		85.0	
		Q25, Q75	68.5, 108.5		78.0, 100.0		67.0, 111.0	
		Min, Max	18, 168		53, 150		41, 144	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.27.2 Descriptive Statistics of hs-CRP (mg/L), homocysteine (umol/L), blood glucose (mg/dL), LDL (mg/dL), HDL (mg/dL), TG (mg/dL), TC (mg/dL), Apo A1 (mg/dL), and Apo B (mg/dL) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Apo B (mg/dL)	Day 90	n	80	80	41	41	39	39
		Mean (SD)	85.9 (26.98)	-2.0 (14.99)	89.0 (23.74)	-1.8 (10.56)	90.1 (28.69)	1.1 (19.94)
		95% CI	79.8, 91.9	-5.3, 1.4	81.5, 96.6	-5.2, 1.6	80.7, 99.4	-5.4, 7.6
		Median	86.0	-0.5	91.0	-1.0	94.0	0.0
		Q25, Q75	66.5, 99.5	-11.6, 5.5	69.0, 102.0	-6.9, 2.7	64.0, 110.0	-7.5, 5.4
		Min, Max	18, 180	-35, 43	44, 154	-24, 23	46, 147	-41, 75

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.28.1 Descriptive Statistics of Fibrinogen (mg/dL)- PP Set****Parameter (units):Fibrinogen (mg/dL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	72		35		22	
	Missing, n (%)	3 (4.0)		0		2 (8.3)	
	Geometric Mean (CV%)	327.8 (24.38)		326.4 (21.03)		329.7 (24.97)	
	95% CI of Geometric Mean	309.8, 346.9		303.9, 350.7		295.6, 367.7	
	Median	318.0		319.0		332.5	
	Q25, Q75	273.5, 367.5		282.0, 381.0		264.0, 408.0	
	Min, Max	200, 564		228, 491		226, 531	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.28.1 Descriptive Statistics of Fibrinogen (mg/dL)- PP Set****Parameter (units):Fibrinogen (mg/dL)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34		11	
	Missing, n (%)	0		0		2 (15.4)	
	Geometric Mean (CV%)	324.4 (24.93)		323.4 (21.03)		306.3 (28.36)	
	95% CI of Geometric Mean	299.8, 350.9		300.7, 347.7		254.1, 369.3	
	Median	325.0		312.0		311.0	
	Q25, Q75	264.0, 399.5		282.0, 379.0		236.0, 408.0	
	Min, Max	200, 529		228, 491		217, 457	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.28.1 Descriptive Statistics of Fibrinogen (mg/dL)- PP Set****Parameter (units):Fibrinogen (mg/dL)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	40	34	34	13	11
	Missing, n (%)		0		0		2 (15.4)
	Geometric Mean (CV%)	302.2 (25.87)		312.2 (20.53)		288.3 (25.23)	
	95% CI of Geometric Mean	278.5, 327.9		290.7, 335.1		248.0, 335.0	
	Median	302.5	-6.3	311.0	-2.7	255.0	-2.9
	Q25, Q75	249.0, 357.5	-18.7, 1.9	269.0, 344.0	-9.8, 2.6	235.0, 339.0	-20.9, 4.6
	Min, Max	172, 526	-31, 34	235, 614	-33, 42	224, 430	-38, 15

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.28.1 Descriptive Statistics of Fibrinogen (mg/dL)- PP Set****Parameter (units):Fibrinogen (mg/dL)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35		12	
	Geometric Mean (CV%)	324.9 (27.04)		325.2 (20.99)		305.7 (26.95)	
	95% CI of Geometric Mean	298.0, 354.2		302.7, 349.2		258.3, 361.8	
	Median	323.0		313.0		306.5	
	Q25, Q75	259.0, 401.0		282.0, 381.0		239.0, 391.5	
	Min, Max	200, 559		228, 491		217, 457	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Appendix 15.3.3.2

Study ID:ZRHM-REXA-08-US

Program:t_fibrino_pp.sas

Status: Final

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**Table 15.2.4.28.1 Descriptive Statistics of Fibrinogen (mg/dL)- PP Set****Parameter (units):Fibrinogen (mg/dL)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	35	35	12	12
	Geometric Mean (CV%)	308.2 (28.44)		298.4 (19.50)		291.8 (21.17)	
	95% CI of Geometric Mean	281.5, 337.4		279.2, 318.9		255.4, 333.3	
	Median	293.0	-6.6	295.0	-6.6	290.0	-2.5
	Q25, Q75	242.0, 366.0	-14.0, 3.5	250.0, 343.0	-18.3, -0.3	238.5, 359.0	-15.8, 4.1
	Min, Max	213, 593	-25, 38	230, 428	-35, 41	216, 391	-35, 56

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.28.1 Descriptive Statistics of Fibrinogen (mg/dL)- PP Set****Parameter (units):Fibrinogen (mg/dL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Geometric Mean (CV%)	322.7 (25.29)		328.9 (21.30)		298.7 (30.79)	
	95% CI of Geometric Mean	299.9, 347.2		304.8, 354.9		237.0, 376.5	
	Median	315.0		320.5		251.0	
	Q25, Q75	260.0, 398.0		282.5, 387.0		236.0, 408.0	
	Min, Max	200, 559		228, 491		217, 457	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.28.1 Descriptive Statistics of Fibrinogen (mg/dL)- PP Set****Parameter (units):Fibrinogen (mg/dL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	Geometric Mean (CV%)	303.5 (26.85)		311.8 (20.30)		294.2 (29.08)	
	95% CI of Geometric Mean	280.8, 328.0		290.0, 335.3		236.3, 366.2	
	Median	285.0	-7.9	304.5	-4.9	255.0	-2.2
	Q25, Q75	248.0, 370.0	-16.3, 2.1	273.0, 350.5	-17.8, 4.3	231.0, 388.0	-5.4, 2.2
	Min, Max	210, 540	-29, 56	219, 570	-38, 93	220, 454	-15, 9

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

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Status: Final

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**Table 15.2.4.28.2 Descriptive Statistics of Fibrinogen (mg/dL)- FAS****Parameter (units):Fibrinogen (mg/dL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	77		41		36	
	Missing, n(%)	3 (3.8)		0		3 (7.7)	
	Geometric Mean (CV%)	327.4 (23.66)		327.4 (21.42)		331.1 (26.70)	
	95% CI of Geometric Mean	310.5, 345.3		306.2, 350.1		302.9, 361.8	
	Median	317.0		319.0		332.5	
	Q25, Q75	277.0, 358.0		283.0, 379.0		260.0, 418.5	
	Min, Max	200, 564		228, 524		217, 543	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.28.2 Descriptive Statistics of Fibrinogen (mg/dL)- FAS****Parameter (units):Fibrinogen (mg/dL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	80	77	41	41	38	36
	Missing, n(%)	0	3 (3.8)	0	0	1 (2.6)	3 (7.7)
	Geometric Mean (CV%)	302.5 (23.02)		310.1 (19.46)		312.2 (26.35)	
	95% CI of Geometric Mean	287.5, 318.2		291.7, 329.6		286.7, 340.0	
	Median	296.5	-6.7	311.0	-2.6	294.0	-2.5
	Q25, Q75	252.5, 355.0	-19.0, 0.8	269.0, 344.0	-10.2, 2.6	251.0, 382.0	-13.4, 2.4
	Min, Max	172, 533	-54, 34	235, 614	-47, 42	224, 554	-38, 25

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.28.2 Descriptive Statistics of Fibrinogen (mg/dL)- FAS****Parameter (units):Fibrinogen (mg/dL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	80	77	41	41	38	36
	Missing, n(%)	0	3 (3.8)	0	0	1 (2.6)	3 (7.7)
	Geometric Mean (CV%)	299.5 (22.75)		297.3 (18.42)		314.1 (27.16)	
	95% CI of Geometric Mean	284.9, 314.9		280.6, 315.0		287.7, 343.0	
	Median	292.5	-8.1	291.0	-6.6	299.5	-4.2
	Q25, Q75	250.0, 345.0	-17.6, 1.9	254.0, 336.0	-18.3, -0.3	246.0, 383.0	-13.8, 2.2
	Min, Max	213, 593	-45, 45	230, 428	-43, 41	203, 541	-35, 56

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.28.2 Descriptive Statistics of Fibrinogen (mg/dL)- FAS****Parameter (units):Fibrinogen (mg/dL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	80	77	41	41	38	36
	Missing, n(%)	0	3 (3.8)	0	0	1 (2.6)	3 (7.7)
	Geometric Mean (CV%)	304.1 (24.09)		306.6 (18.75)		317.9 (25.90)	
	95% CI of Geometric Mean	288.4, 320.7		289.1, 325.1		292.3, 345.7	
	Median	291.5	-7.9	298.0	-5.8	307.5	-2.2
	Q25, Q75	251.5, 348.5	-16.3, 1.6	272.0, 349.0	-17.4, 3.9	255.0, 388.0	-13.4, 1.4
	Min, Max	210, 580	-50, 56	219, 570	-47, 93	220, 584	-28, 26

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.29.1 Descriptive Statistics of HbA1c (%) - PP Set****Parameter (units): Hemoglobin A1C (%)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Mean (SD)	5.5 (0.44)		5.3 (0.35)		5.6 (0.48)	
	95% CI	5.3, 5.6		5.2, 5.4		5.4, 5.8	
	Median	5.4		5.2		5.5	
	Q25, Q75	5.1, 5.7		5.0, 5.5		5.3, 5.9	
	Min, Max	5, 7		5, 6		5, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Appendix 15.3.3.2

Study ID: ZRHM-REXA-08-US

Program: t_hba1c_pp.sas

Status: Final

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**Table 15.2.4.29.1 Descriptive Statistics of HbA1c (%) - PP Set****Parameter (units): Hemoglobin A1C (%)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34		13	
	Mean (SD)	5.5 (0.54)		5.3 (0.35)		5.7 (0.54)	
	95% CI	5.3, 5.7		5.2, 5.4		5.4, 6.0	
	Median	5.5		5.3		5.6	
	Q25, Q75	5.1, 5.7		5.1, 5.5		5.4, 5.7	
	Min, Max	5, 7		5, 6		5, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Appendix 15.3.3.2

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Status: Final

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**Table 15.2.4.29.1 Descriptive Statistics of HbA1c (%) - PP Set****Parameter (units): Hemoglobin A1C (%)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35		12	
	Mean (SD)	5.5 (0.51)		5.3 (0.35)		5.7 (0.58)	
	95% CI	5.3, 5.7		5.2, 5.4		5.3, 6.0	
	Median	5.5		5.3		5.5	
	Q25, Q75	5.1, 5.7		5.0, 5.5		5.3, 5.8	
	Min, Max	5, 7		5, 6		5, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

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**Table 15.2.4.29.1 Descriptive Statistics of HbA1c (%) - PP Set**

Parameter (units): Hemoglobin A1C (%)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	5.4 (0.49)		5.3 (0.36)		5.5 (0.24)	
	95% CI	5.3, 5.6		5.2, 5.4		5.3, 5.7	
	Median	5.4		5.3		5.5	
	Q25, Q75	5.1, 5.7		5.1, 5.5		5.4, 5.6	
	Min, Max	5, 7		5, 6		5, 6	
Day 90	n	47	47	32	32	9	9
	Mean (SD)	5.5 (0.47)	0.7 (4.83)	5.4 (0.34)	2.0 (4.29)	5.3 (0.35)	-2.4 (5.93)
	95% CI	5.3, 5.6	-0.7, 2.1	5.3, 5.5	0.4, 3.5	5.1, 5.6	-6.9, 2.2
	Median	5.5	1.7	5.5	2.7	5.3	-1.8
	Q25, Q75	5.1, 5.7	-1.9, 3.6	5.2, 5.6	-0.9, 5.0	5.1, 5.5	-8.9, 1.9
	Min, Max	5, 7	-14, 10	5, 6	-9, 10	5, 6	-9, 6

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.29.2 Descriptive Statistics of HbA1c (%) - FAS****Parameter (units): Hemoglobin A1C (%)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41		39	
	Mean (SD)	5.5 (0.43)		5.3 (0.34)		5.6 (0.49)	
	95% CI	5.4, 5.6		5.2, 5.4		5.4, 5.7	
	Median	5.4		5.3		5.5	
	Q25, Q75	5.1, 5.7		5.0, 5.5		5.3, 5.8	
	Min, Max	5, 7		5, 6		5, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Appendix 15.3.3.2

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Status: Final

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**Table 15.2.4.29.2 Descriptive Statistics of HbA1c (%) - FAS****Parameter (units): Hemoglobin A1C (%)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	80	80	41	41	39	39
	Mean (SD)	5.4 (0.40)	-0.2 (4.60)	5.4 (0.33)	1.4 (3.97)	5.5 (0.59)	-0.4 (5.30)
	95% CI	5.3, 5.5	-1.2, 0.8	5.2, 5.5	0.1, 2.7	5.3, 5.7	-2.1, 1.4
	Median	5.4	0.0	5.3	0.0	5.5	0.0
	Q25, Q75	5.2, 5.7	-2.8, 2.0	5.1, 5.6	0.0, 4.3	5.2, 5.7	-3.5, 3.6
	Min, Max	5, 7	-14, 10	5, 6	-9, 10	5, 8	-11, 13

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

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**Table 15.2.4.30.1 Descriptive Statistics of sICAM (ng/mL)- PP Set****Parameter (units): Intercellular Adhesion Molecule 1 (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	73		35		24	
	Missing, n (%)	2 (2.7)		0		0	
	BLOQ, n (%)	2 (2.7)		0		0	
	Geometric Mean (CV%)	238.8 (51.68)		241.8 (40.39)		236.0 (30.60)	
	95% CI of Geometric Mean	213.1, 267.6		211.5, 276.3		208.0, 267.8	
	Median	255.3		247.4		238.5	
	Q25, Q75	213.3, 305.9		205.4, 290.9		204.2, 282.8	
	Min, Max	21, 498		73, 472		124, 380	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.30.1 Descriptive Statistics of sICAM (ng/mL)- PP Set****Parameter (units): Intercellular Adhesion Molecule 1 (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	75	73	35	35	24	24
	Missing, n (%)	0	2 (2.7)	0	0	0	0
	BLOQ, n (%)	2 (2.7)	0	0	0	0	0
	Geometric Mean (CV%)	225.1 (49.89)		247.8 (39.77)		224.9 (31.31)	
	95% CI of Geometric Mean	201.9, 250.9		217.2, 282.7		197.6, 255.9	
	Median	244.4	-5.0	251.4	0.0	233.6	-10.2
	Q25, Q75	216.7, 289.4	-12.3, 1.5	207.9, 304.0	-5.3, 10.0	201.7, 273.7	-16.5, 6.1
	Min, Max	21, 396	-31, 44	86, 525	-22, 85	101, 374	-21, 60

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.30.1 Descriptive Statistics of sICAM (ng/mL)- PP Set****Parameter (units): Intercellular Adhesion Molecule 1 (ng/mL)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	39		34		13	
	Missing, n (%)	1 (2.5)		0		0	
	BLOQ, n (%)	1 (2.6)		0		0	
	Geometric Mean (CV%)	247.2 (54.32)		238.3 (42.19)		220.0 (32.62)	
	95% CI of Geometric Mean	209.6, 291.5		206.8, 274.5		181.5, 266.6	
	Median	265.8		244.5		225.1	
	Q25, Q75	205.3, 331.6		205.4, 283.4		193.7, 251.4	
	Min, Max	21, 498		73, 472		124, 380	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.30.1 Descriptive Statistics of sICAM (ng/mL)- PP Set**

Parameter (units):Intercellular Adhesion Molecule 1 (ng/mL)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	39	34	34	13	13
	Missing, n (%)	0	1 (2.5)	0	0	0	0
	BLOQ, n (%)	1 (2.5)	0	0	0	0	0
	Geometric Mean (CV%)	230.6 (53.63)		245.9 (46.21)		208.4 (36.68)	
	95% CI of Geometric Mean	196.3, 270.9		210.8, 286.7		168.1, 258.3	
	Median	252.0	-4.0	247.4	1.6	217.6	-6.5
	Q25, Q75	205.5, 312.3	-14.9, 5.8	201.7, 317.0	-7.1, 9.9	185.8, 251.9	-14.4, -1.5
	Min, Max	21, 434	-32, 22	83, 608	-23, 80	106, 375	-20, 35

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.30.1 Descriptive Statistics of sICAM (ng/mL)- PP Set****Parameter (units): Intercellular Adhesion Molecule 1 (ng/mL)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	37		35		12	
	Missing, n (%)	2 (5.1)		0		0	
	Geometric Mean (CV%)	261.8 (31.36)		234.5 (42.74)		212.6 (35.85)	
	95% CI of Geometric Mean	236.4, 290.0		203.7, 270.0		170.4, 265.1	
	Median	265.8		241.6		216.2	
	Q25, Q75	224.3, 316.4		197.6, 283.4		173.1, 271.1	
	Min, Max	117, 498		73, 472		124, 380	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.30.1 Descriptive Statistics of sICAM (ng/mL)- PP Set****Parameter (units): Intercellular Adhesion Molecule 1 (ng/mL)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	37	35	35	12	12
	Missing, n (%)	0	2 (5.1)	0	0	0	0
	Geometric Mean (CV%)	235.1 (33.49)		240.4 (47.78)		200.4 (39.38)	
	95% CI of Geometric Mean	211.4, 261.3		205.7, 281.0		157.4, 255.1	
	Median	238.6	-3.2	239.4	0.8	187.6	-4.6
	Q25, Q75	199.9, 276.4	-17.3, 5.6	204.9, 307.4	-9.3, 10.4	157.2, 240.3	-13.0, 4.7
	Min, Max	108, 472	-36, 38	69, 518	-25, 113	120, 479	-34, 26

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.30.1 Descriptive Statistics of sICAM (ng/mL)- PP Set****Parameter (units): Intercellular Adhesion Molecule 1 (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	45		32		9	
	Missing, n (%)	2 (4.3)		0		0	
	Geometric Mean (CV%)	263.3 (29.83)		239.6 (40.59)		211.1 (37.96)	
	95% CI of Geometric Mean	241.1, 287.5		208.1, 275.9		159.2, 280.0	
	Median	265.8		244.0		221.3	
	Q25, Q75	224.3, 321.1		201.5, 282.7		191.9, 259.7	
	Min, Max	117, 498		73, 472		124, 380	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.30.1 Descriptive Statistics of sICAM (ng/mL)- PP Set****Parameter (units): Intercellular Adhesion Molecule 1 (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	45	32	32	9	9
	Missing, n (%)	0	2 (4.3)	0	0	0	0
	Geometric Mean (CV%)	236.7 (28.97)		249.6 (40.65)		203.4 (50.57)	
	95% CI of Geometric Mean	217.8, 257.4		216.8, 287.5		140.9, 293.6	
	Median	250.0	-6.7	249.7	5.4	200.7	-8.1
	Q25, Q75	207.7, 283.1	-14.6, 6.7	219.5, 285.2	-5.3, 14.2	176.3, 254.8	-12.4, 7.3
	Min, Max	108, 411	-46, 23	85, 521	-21, 43	108, 511	-29, 34

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.30.2 Descriptive Statistics of sICAM (ng/mL)- FAS****Parameter (units): Inter cellular Adhesion Molecule 1 (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	78		41		39	
	Missing, n (%)	2 (2.5)		0		0	
	BLOQ, n (%)	2 (2.6)		0		1 (2.6)	
	Geometric Mean (CV%)	241.9 (51.00)		243.0 (40.69)		225.5 (50.39)	
	95% CI of Geometric Mean	217.0, 269.7		214.7, 275.0		193.2, 263.1	
	Median	258.3		262.0		237.4	
	Q25, Q75	213.3, 308.1		214.8, 296.8		193.7, 305.4	
	Min, Max	21, 498		73, 472		21, 380	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.30.2 Descriptive Statistics of sICAM (ng/mL)- FAS****Parameter (units): Inter cellular Adhesion Molecule 1 (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	%	Value	%	Value	%
			Change(*)		Change(*)		Change(*)
Day 6/Discharge Confinement	n	80	78	41	41	39	39
	Missing, n (%)	0	2 (2.5)	0	0	0	0
	BLOQ, n (%)	2 (2.5)	0	0	0	1 (2.6)	0
	Geometric Mean (CV%)	229.6 (49.44)		248.0 (40.30)		220.5 (51.98)	
	95% CI of Geometric Mean	206.9, 254.8		219.4, 280.4		188.1, 258.4	
	Median	244.7	-4.9	260.7	0.0	236.6	0.0
	Q25, Q75	217.6, 297.3	-12.5, 1.5	210.1, 310.2	-5.3, 9.8	193.5, 275.9	-13.4, 5.6
	Min, Max	21, 417	-31, 94	86, 525	-22, 85	21, 476	-21, 68

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.30.2 Descriptive Statistics of sICAM (ng/mL)- FAS****Parameter (units): Inter cellular Adhesion Molecule 1 (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	%	Value	%	Value	%
			Change(*)		Change(*)		Change(*)
Day 30	n	80	78	41	41	39	39
	Missing, n (%)	0	2 (2.5)	0	0	0	0
	BLOQ, n (%)	2 (2.5)	0	0	0	1 (2.6)	0
	Geometric Mean (CV%)	228.9 (51.55)		252.3 (44.83)		219.2 (51.99)	
	95% CI of Geometric Mean	205.4, 255.0		220.4, 288.9		187.0, 256.9	
	Median	241.3	-3.6	251.2	1.9	241.9	-1.7
	Q25, Q75	212.4, 294.4	-12.5, 4.2	201.7, 339.2	-6.6, 9.9	188.6, 288.1	-14.5, 2.6
	Min, Max	21, 434	-32, 44	83, 608	-23, 80	21, 448	-24, 53

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.30.2 Descriptive Statistics of sICAM (ng/mL)- FAS****Parameter (units): Inter cellular Adhesion Molecule 1 (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	80	78	41	41	39	39
	Missing, n (%)	0	2 (2.5)	0	0	0	0
	BLOQ, n (%)	2 (2.5)	0	0	0	1 (2.6)	0
	Geometric Mean (CV%)	225.3 (50.73)		250.2 (46.12)		217.2 (51.96)	
	95% CI of Geometric Mean	202.5, 250.7		217.7, 287.4		185.3, 254.5	
	Median	239.7	-2.9	243.3	0.8	232.5	-1.7
	Q25, Q75	203.3, 275.7	-14.9, 5.0	206.3, 337.2	-7.0, 10.9	187.6, 280.7	-13.9, 2.6
	Min, Max	21, 472	-41, 43	69, 518	-25, 113	21, 479	-34, 37

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.30.2 Descriptive Statistics of sICAM (ng/mL)- FAS****Parameter (units): Inter cellular Adhesion Molecule 1 (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	%	Value	%	Value	%
			Change(*)		Change(*)		Change(*)
Day 90	n	80	78	41	41	39	39
	Missing, n (%)	0	2 (2.5)	0	0	0	0
	BLOQ, n (%)	2 (2.5)	0	0	0	1 (2.6)	0
	Geometric Mean (CV%)	228.8 (50.31)		253.2 (42.66)		225.6 (56.00)	
	95% CI of Geometric Mean	205.8, 254.3		222.5, 288.2		190.4, 267.2	
	Median	250.8	-2.8	251.2	5.4	236.5	-1.3
	Q25, Q75	203.2, 290.9	-12.5, 8.2	221.6, 310.2	-5.7, 14.7	191.7, 295.1	-12.3, 6.4
	Min, Max	21, 442	-46, 41	85, 552	-22, 68	21, 511	-29, 190

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Leukocytes (GI/L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Mean (SD)	7.885 (1.6848)		8.494 (1.8623)		7.851 (2.3725)	
	95% CI	7.490, 8.280		7.850, 9.140		6.840, 8.860	
	Median	7.690		8.610		7.545	
	Q25, Q75	6.780, 8.710		6.940, 10.140		6.130, 9.600	
	Min, Max	4.68, 13.07		5.13, 11.97		3.59, 13.55	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Leukocytes (GI/L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	75	75	35	35	24	24
	Mean (SD)	7.510 (1.7908)	-4.044 (16.7705)	8.418 (1.8464)	0.057 (14.1927)	6.946 (1.5896)	-9.059 (13.6644)
	95% CI	7.090, 7.930	-7.910, -0.180	7.780, 9.060	-4.820, 4.940	6.270, 7.620	-14.830, -3.280
	Median	7.500	-6.429	8.350	1.401	6.925	-7.348
	Q25, Q75	6.250, 8.590	-15.161, 7.227	6.690, 9.830	-9.772, 8.453	6.050, 8.120	-18.533, 0.339
	Min, Max	4.07, 11.90	-45.52, 45.66	5.16, 11.54	-38.46, 30.12	3.31, 9.65	-36.02, 22.88

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Leukocytes (GI/L)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34		13	
	Mean (SD)	8.103 (1.7261)		8.305 (1.8730)		7.010 (1.9731)	
	95% CI	7.550, 8.660		7.650, 8.960		5.810, 8.210	
	Median	8.010		7.930		6.670	
	Q25, Q75	6.850, 8.975		6.800, 9.280		5.990, 8.140	
	Min, Max	5.41, 13.07		5.13, 11.97		3.59, 10.94	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Leukocytes (GI/L)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	40	34	34	13	13
	Mean (SD)	7.279 (1.7005)	-9.279 (15.2200)	7.734 (1.8123)	-5.517 (16.7043)	6.225 (1.9096)	-9.125 (21.8167)
	95% CI	6.730, 7.830	-14.150, -4.410	7.100, 8.370	-11.350, 0.320	5.070, 7.380	-22.310, 4.060
	Median	6.645	-11.596	7.675	-5.347	5.790	-15.025
	Q25, Q75	6.190, 7.880	-20.030, -4.242	5.950, 8.520	-17.740, 5.848	5.090, 7.060	-22.283, -2.507
	Min, Max	4.63, 11.35	-34.39, 38.38	4.73, 12.45	-41.32, 33.03	3.50, 11.26	-39.19, 33.89

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Leukocytes (GI/L)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35		12	
	Mean (SD)	8.306 (1.7640)		8.373 (1.8881)		6.890 (1.8707)	
	95% CI	7.730, 8.880		7.720, 9.030		5.700, 8.080	
	Median	8.140		8.010		6.770	
	Q25, Q75	7.280, 9.180		6.800, 9.930		5.755, 7.850	
	Min, Max	5.41, 13.07		5.13, 11.97		3.59, 10.94	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Leukocytes (GI/L)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	35	35	12	12
	Mean (SD)	7.505 (1.6992)	-8.479 (16.9173)	7.593 (1.6315)	-8.127 (13.8351)	6.110 (1.5611)	-9.411 (17.3028)
	95% CI	6.950, 8.060	-13.970, -2.990	7.030, 8.160	-12.880, -3.370	5.110, 7.110	-20.410, 1.590
	Median	7.370	-10.406	7.760	-8.370	6.065	-1.723
	Q25, Q75	6.350, 8.470	-21.843, 2.567	6.330, 8.450	-17.561, 5.049	5.030, 7.435	-21.992, 3.421
	Min, Max	4.68, 11.71	-35.83, 34.38	4.82, 10.45	-35.40, 18.16	3.21, 8.66	-42.96, 8.67

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Leukocytes (GI/L)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	8.321 (1.7466)		8.266 (1.7920)		6.850 (2.1511)	
	95% CI	7.800, 8.840		7.610, 8.920		5.190, 8.510	
	Median	8.140		7.930		6.110	
	Q25, Q75	7.000, 9.290		6.870, 9.235		5.520, 8.140	
	Min, Max	5.41, 13.07		5.13, 11.97		3.59, 10.94	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Leukocytes (GI/L)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	32	32	9	9
	Mean (SD)	7.330 (1.6676)	-10.430 (18.9373)	7.172 (1.9558)	-12.548 (18.1189)	5.369 (1.3462)	-19.290 (15.1553)
	95% CI	6.840, 7.820	-15.990, -4.860	6.460, 7.880	-19.090, -6.010	4.330, 6.410	-30.940, -7.640
	Median	6.910	-12.228	6.515	-14.037	5.650	-22.975
	Q25, Q75	6.090, 8.390	-24.726, 1.206	5.690, 8.585	-22.445, -6.574	4.830, 5.800	-28.804, -17.840
	Min, Max	4.30, 10.69	-47.17, 53.29	4.47, 11.87	-40.45, 37.86	3.24, 7.87	-32.46, 16.24

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Neutrophils (GI/L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Mean (SD)	4.482 (1.3885)		4.825 (1.5055)		4.369 (1.8002)	
	95% CI	4.160, 4.810		4.300, 5.350		3.600, 5.130	
	Median	4.390		4.620		4.165	
	Q25, Q75	3.580, 5.190		3.670, 6.260		2.970, 5.400	
	Min, Max	1.89, 8.64		2.48, 8.11		1.39, 10.01	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Neutrophils (GI/L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	75	75	35	35	24	24
	Mean (SD)	4.208 (1.4092)	-4.787 (24.5272)	4.749 (1.3847)	1.301 (21.2177)	3.665 (1.2204)	-12.468 (22.5892)
	95% CI	3.880, 4.540	-10.440, 0.860	4.270, 5.230	-5.990, 8.590	3.150, 4.190	-22.010, -2.920
	Median	4.190	-9.266	4.820	0.000	3.830	-15.650
	Q25, Q75	3.230, 5.190	-19.335, 6.796	3.700, 5.780	-14.242, 16.894	2.480, 4.685	-26.520, -0.818
	Min, Max	1.35, 7.48	-58.70, 90.35	2.41, 7.18	-54.38, 39.37	1.02, 5.52	-54.26, 49.32

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Neutrophils (GI/L)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34		13	
	Mean (SD)	4.608 (1.4826)		4.712 (1.5452)		3.750 (1.3426)	
	95% CI	4.130, 5.090		4.170, 5.260		2.930, 4.570	
	Median	4.545		4.500		3.360	
	Q25, Q75	3.750, 5.190		3.630, 6.260		2.950, 4.350	
	Min, Max	1.99, 8.39		2.48, 8.11		1.39, 6.36	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Neutrophils (GI/L)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	40	34	34	13	13
	Mean (SD)	4.035 (1.5099)	-11.743 (20.3358)	4.365 (1.4425)	-3.067 (27.2897)	3.069 (1.1399)	-14.146 (28.1935)
	95% CI	3.550, 4.520	-18.250, -5.230	3.860, 4.870	-12.590, 6.460	2.380, 3.760	-31.190, 2.900
	Median	3.805	-14.940	4.125	-0.938	2.860	-21.053
	Q25, Q75	3.085, 4.500	-23.065, -6.249	3.160, 5.070	-26.997, 15.200	2.640, 3.480	-28.383, -3.051
	Min, Max	1.37, 7.94	-41.95, 55.64	2.49, 8.22	-56.97, 62.28	1.38, 6.20	-42.83, 64.89

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Neutrophils (GI/L)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35		12	
	Mean (SD)	4.831 (1.4377)		4.736 (1.5292)		3.548 (1.2293)	
	95% CI	4.360, 5.300		4.210, 5.270		2.760, 4.330	
	Median	4.760		4.510		3.315	
	Q25, Q75	3.830, 5.470		3.630, 6.260		2.920, 4.175	
	Min, Max	2.12, 8.64		2.48, 8.11		1.39, 6.36	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Neutrophils (GI/L)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	35	35	12	12
	Mean (SD)	4.266 (1.2634)	-9.628 (21.1960)	4.245 (1.2221)	-6.986 (21.0213)	2.911 (0.8931)	-13.655 (21.5991)
	95% CI	3.850, 4.680	-16.500, -2.750	3.820, 4.670	-14.210, 0.240	2.340, 3.480	-27.380, 0.070
	Median	4.290	-11.517	4.250	-9.530	2.815	-7.387
	Q25, Q75	3.100, 4.910	-25.038, 0.000	3.390, 4.950	-24.886, 14.141	2.315, 3.440	-27.116, 3.036
	Min, Max	1.87, 7.08	-44.65, 48.44	2.11, 7.50	-47.97, 26.13	1.36, 4.71	-64.31, 11.30

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set****Parameter (units): Neutrophils (GI/L)**
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	4.810 (1.4378)		4.676 (1.5194)		3.646 (1.4201)	
	95% CI	4.380, 5.240		4.120, 5.230		2.550, 4.740	
	Median	4.660		4.500		3.270	
	Q25, Q75	3.830, 5.470		3.650, 5.725		2.890, 4.590	
	Min, Max	2.12, 8.64		2.48, 8.11		1.39, 6.36	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Neutrophils (GI/L)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	32	32	9	9
	Mean (SD)	4.514 (1.3301)	-1.816 (31.7904)	4.452 (1.4657)	-0.957 (29.0098)	2.921 (0.9356)	-14.174 (27.8344)
	95% CI	4.120, 4.910	-11.160, 7.520	3.920, 4.990	-11.420, 9.510	2.200, 3.650	-35.570, 7.230
	Median	4.250	-8.738	4.170	-6.862	2.810	-26.316
	Q25, Q75	3.550, 5.460	-23.977, 16.617	3.295, 5.300	-22.060, 13.403	2.100, 3.460	-30.283, -7.261
	Min, Max	2.19, 7.71	-53.00, 105.60	1.98, 8.17	-44.79, 72.71	1.74, 4.45	-38.53, 39.10

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Lymphocytes (GI/L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Mean (SD)	2.722 (0.7269)		2.924 (0.6798)		2.834 (0.7229)	
	95% CI	2.550, 2.890		2.690, 3.160		2.520, 3.140	
	Median	2.580		2.840		2.740	
	Q25, Q75	2.200, 3.170		2.450, 3.330		2.195, 3.485	
	Min, Max	1.55, 5.16		1.33, 4.40		1.78, 4.14	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Lymphocytes (GI/L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	75	75	35	35	24	24
	Mean (SD)	2.620 (0.6775)	-2.023 (17.9249)	2.909 (0.6360)	0.920 (15.6396)	2.648 (0.6213)	-5.145 (14.3290)
	95% CI	2.460, 2.780	-6.150, 2.110	2.690, 3.130	-4.460, 6.300	2.380, 2.920	-11.200, 0.910
	Median	2.470	-4.308	2.930	-0.601	2.560	-6.594
	Q25, Q75	2.100, 3.110	-13.778, 8.387	2.470, 3.390	-11.563, 7.797	2.150, 3.040	-12.542, 1.550
	Min, Max	1.40, 4.21	-39.49, 55.17	1.74, 4.33	-18.71, 45.11	1.53, 3.97	-31.97, 36.90

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Lymphocytes (GI/L)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34		13	
	Mean (SD)	2.779 (0.8003)		2.851 (0.6443)		2.740 (0.7468)	
	95% CI	2.520, 3.040		2.620, 3.080		2.280, 3.200	
	Median	2.630		2.770		2.500	
	Q25, Q75	2.150, 3.205		2.390, 3.330		2.210, 3.430	
	Min, Max	1.67, 5.16		1.33, 4.17		1.78, 4.14	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Lymphocytes (GI/L)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	40	34	34	13	13
	Mean (SD)	2.558 (0.6918)	-6.431 (16.5264)	2.635 (0.7312)	-5.867 (21.6588)	2.638 (0.8444)	-2.440 (23.5843)
	95% CI	2.330, 2.780	-11.720, -1.140	2.380, 2.900	-13.430, 1.700	2.120, 3.150	-16.700, 11.820
	Median	2.425	-8.084	2.630	-4.785	2.530	-2.538
	Q25, Q75	2.010, 3.015	-18.005, 2.451	2.090, 3.050	-20.089, 10.963	1.870, 3.180	-12.429, 6.751
	Min, Max	1.23, 4.17	-34.30, 42.27	1.59, 4.63	-50.31, 49.62	1.69, 4.56	-36.40, 58.82

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Lymphocytes (GI/L)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35		12	
	Mean (SD)	2.768 (0.7777)		2.895 (0.6867)		2.757 (0.7429)	
	95% CI	2.510, 3.020		2.650, 3.140		2.280, 3.230	
	Median	2.650		2.780		2.635	
	Q25, Q75	2.140, 3.170		2.390, 3.330		2.195, 3.360	
	Min, Max	1.67, 5.16		1.33, 4.40		1.78, 4.14	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Lymphocytes (GI/L)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	35	35	12	12
	Mean (SD)	2.572 (0.6910)	-4.674 (21.5447)	2.684 (0.6289)	-5.588 (17.2993)	2.688 (0.8379)	-2.033 (16.6618)
	95% CI	2.340, 2.800	-11.660, 2.310	2.460, 2.900	-11.540, 0.360	2.150, 3.220	-12.620, 8.560
	Median	2.490	-3.834	2.690	-6.441	2.420	-1.503
	Q25, Q75	1.980, 3.010	-25.888, 8.235	2.100, 3.230	-18.056, 2.679	2.075, 3.255	-9.910, 8.693
	Min, Max	1.46, 4.23	-38.37, 58.08	1.59, 4.15	-50.31, 45.87	1.63, 4.39	-39.46, 26.20

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Lymphocytes (GI/L)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	2.807 (0.7983)		2.883 (0.7031)		2.609 (0.7889)	
	95% CI	2.570, 3.050		2.620, 3.140		2.000, 3.220	
	Median	2.710		2.770		2.370	
	Q25, Q75	2.140, 3.500		2.345, 3.330		2.180, 2.940	
	Min, Max	1.67, 5.16		1.33, 4.40		1.78, 4.14	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Lymphocytes (GI/L)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	32	32	9	9
	Mean (SD)	2.188 (0.5655)	-19.315 (19.3243)	2.100 (0.5454)	-25.828 (16.0196)	1.992 (0.6319)	-22.850 (15.4208)
	95% CI	2.020, 2.360	-24.990, -13.640	1.900, 2.300	-31.610, -20.050	1.500, 2.480	-34.710, -10.990
	Median	2.070	-23.856	2.050	-26.194	1.710	-25.281
	Q25, Q75	1.730, 2.500	-35.084, -3.434	1.670, 2.410	-35.168, -20.786	1.500, 2.640	-32.127, -19.774
	Min, Max	1.34, 3.82	-51.80, 23.95	1.19, 3.50	-47.63, 42.86	1.33, 2.91	-41.84, 11.39

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Monocytes (GI/L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Mean (SD)	0.419 (0.1175)		0.460 (0.1590)		0.395 (0.1474)	
	95% CI	0.390, 0.450		0.400, 0.520		0.330, 0.460	
	Median	0.400		0.420		0.365	
	Q25, Q75	0.330, 0.500		0.350, 0.570		0.285, 0.490	
	Min, Max	0.22, 0.79		0.18, 0.80		0.18, 0.69	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Monocytes (GI/L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	75	75	35	35	24	24
	Mean (SD)	0.450 (0.1146)	11.099 (25.6961)	0.475 (0.1364)	8.188 (26.3822)	0.420 (0.1382)	10.945 (27.5754)
	95% CI	0.420, 0.480	5.180, 17.020	0.420, 0.530	-0.880, 17.260	0.360, 0.480	-0.700, 22.590
	Median	0.460	12.000	0.510	10.714	0.390	3.226
	Q25, Q75	0.370, 0.520	-5.714, 30.952	0.340, 0.560	-3.125, 19.444	0.320, 0.480	-8.236, 24.037
	Min, Max	0.22, 0.80	-59.70, 75.76	0.20, 0.75	-63.24, 85.71	0.22, 0.75	-26.19, 72.73

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Monocytes (GI/L)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34		13	
	Mean (SD)	0.448 (0.1058)		0.464 (0.1609)		0.324 (0.1260)	
	95% CI	0.410, 0.490		0.400, 0.520		0.240, 0.400	
	Median	0.450		0.425		0.290	
	Q25, Q75	0.375, 0.530		0.350, 0.570		0.270, 0.340	
	Min, Max	0.22, 0.70		0.18, 0.80		0.18, 0.69	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Monocytes (GI/L)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	40	34	34	13	13
	Mean (SD)	0.448 (0.1406)	1.088 (23.1925)	0.464 (0.1394)	5.111 (30.6972)	0.317 (0.0966)	2.843 (29.8682)
	95% CI	0.400, 0.500	-6.330, 8.510	0.410, 0.520	-5.600, 15.830	0.250, 0.380	-15.210, 20.900
	Median	0.430	-0.909	0.435	2.165	0.290	0.000
	Q25, Q75	0.375, 0.530	-17.071, 17.155	0.350, 0.600	-15.000, 17.143	0.260, 0.400	-10.345, 11.111
	Min, Max	0.22, 1.03	-45.00, 47.14	0.20, 0.73	-34.88, 116.67	0.20, 0.53	-40.58, 76.67

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Monocytes (GI/L)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35		12	
	Mean (SD)	0.441 (0.1086)		0.461 (0.1593)		0.365 (0.1565)	
	95% CI	0.400, 0.480		0.400, 0.520		0.260, 0.470	
	Median	0.450		0.420		0.315	
	Q25, Q75	0.360, 0.510		0.350, 0.570		0.280, 0.390	
	Min, Max	0.24, 0.70		0.18, 0.80		0.18, 0.69	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Monocytes (GI/L)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	35	35	12	12
	Mean (SD)	0.444 (0.1532)	5.042 (43.3091)	0.416 (0.1476)	-5.379 (28.8986)	0.318 (0.1403)	-9.548 (31.4542)
	95% CI	0.390, 0.500	-9.000, 19.090	0.360, 0.470	-15.310, 4.550	0.220, 0.410	-29.540, 10.440
	Median	0.440	-1.818	0.370	-14.286	0.300	-10.167
	Q25, Q75	0.320, 0.550	-22.222, 25.000	0.290, 0.490	-27.500, 20.513	0.220, 0.390	-29.926, 16.571
	Min, Max	0.13, 0.83	-57.78, 124.32	0.21, 0.73	-69.12, 72.22	0.10, 0.63	-62.96, 36.67

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Monocytes (GI/L)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	0.436 (0.1061)		0.450 (0.1454)		0.356 (0.1355)	
	95% CI	0.400, 0.470		0.390, 0.510		0.250, 0.460	
	Median	0.440		0.420		0.300	
	Q25, Q75	0.360, 0.500		0.355, 0.550		0.290, 0.360	
	Min, Max	0.22, 0.70		0.18, 0.78		0.25, 0.69	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Monocytes (GI/L)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	32	32	9	9
	Mean (SD)	0.434 (0.1766)	0.465 (34.3691)	0.420 (0.1485)	-3.431 (31.7943)	0.314 (0.1639)	-5.394 (57.4677)
	95% CI	0.380, 0.490	-9.630, 10.560	0.360, 0.480	-14.900, 8.040	0.180, 0.450	-49.570, 38.790
	Median	0.410	-4.444	0.405	-8.515	0.290	-12.121
	Q25, Q75	0.300, 0.580	-14.583, 14.815	0.315, 0.525	-21.825, 11.111	0.230, 0.370	-46.377, -5.556
	Min, Max	0.19, 0.98	-60.61, 102.78	0.20, 0.86	-52.56, 120.51	0.07, 0.66	-74.07, 120.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Eosinophils (GI/L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Mean (SD)	0.216 (0.1072)		0.236 (0.1400)		0.200 (0.1196)	
	95% CI	0.190, 0.250		0.180, 0.290		0.140, 0.260	
	Median	0.190		0.190		0.160	
	Q25, Q75	0.140, 0.270		0.150, 0.300		0.120, 0.265	
	Min, Max	0.04, 0.67		0.07, 0.74		0.03, 0.46	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Eosinophils (GI/L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	75	75	35	35	24	24
	Mean (SD)	0.189 (0.0973)	-8.231 (27.1944)	0.234 (0.1677)	0.832 (28.5197)	0.168 (0.0957)	3.241 (67.9558)
	95% CI	0.160, 0.220	-14.490, -1.970	0.170, 0.300	-8.970, 10.630	0.120, 0.210	-25.460, 31.940
	Median	0.170	-11.111	0.190	-5.882	0.140	-11.688
	Q25, Q75	0.120, 0.220	-26.866, 6.667	0.130, 0.270	-20.000, 11.765	0.090, 0.240	-35.652, 0.000
	Min, Max	0.07, 0.51	-58.82, 100.00	0.06, 1.03	-36.84, 90.00	0.05, 0.41	-76.92, 200.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Eosinophils (GI/L)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34		13	
	Mean (SD)	0.217 (0.0903)		0.232 (0.1400)		0.152 (0.0875)	
	95% CI	0.180, 0.250		0.180, 0.290		0.090, 0.210	
	Median	0.195		0.190		0.140	
	Q25, Q75	0.150, 0.255		0.150, 0.280		0.100, 0.170	
	Min, Max	0.09, 0.49		0.07, 0.74		0.03, 0.32	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Eosinophils (GI/L)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	40	34	34	13	13
	Mean (SD)	0.195 (0.0751)	-3.336 (39.6756)	0.217 (0.1217)	-0.978 (31.5033)	0.163 (0.1227)	21.258 (70.5135)
	95% CI	0.170, 0.220	-16.030, 9.360	0.170, 0.260	-11.980, 10.020	0.080, 0.240	-21.360, 63.870
	Median	0.190	-12.250	0.195	-9.109	0.140	0.000
	Q25, Q75	0.145, 0.230	-30.536, 11.263	0.130, 0.270	-25.000, 12.500	0.080, 0.190	-18.750, 26.667
	Min, Max	0.06, 0.37	-60.00, 120.00	0.05, 0.64	-55.81, 70.59	0.04, 0.52	-58.82, 166.67

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Eosinophils (GI/L)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35		12	
	Mean (SD)	0.217 (0.0885)		0.233 (0.1384)		0.176 (0.1168)	
	95% CI	0.180, 0.250		0.180, 0.290		0.100, 0.260	
	Median	0.190		0.190		0.145	
	Q25, Q75	0.150, 0.260		0.150, 0.300		0.105, 0.265	
	Min, Max	0.09, 0.49		0.07, 0.74		0.03, 0.41	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Eosinophils (GI/L)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	35	35	12	12
	Mean (SD)	0.171 (0.0882)	-17.890 (31.6936)	0.201 (0.1370)	-11.962 (37.2126)	0.152 (0.1134)	-2.801 (46.5885)
	95% CI	0.140, 0.200	-28.170, -7.610	0.150, 0.250	-24.750, 0.830	0.070, 0.230	-32.410, 26.810
	Median	0.160	-20.000	0.160	-15.790	0.100	-26.481
	Q25, Q75	0.120, 0.210	-40.909, -6.667	0.120, 0.250	-30.233, 0.000	0.070, 0.205	-31.667, 11.277
	Min, Max	0.07, 0.48	-73.08, 75.00	0.05, 0.60	-70.00, 140.00	0.06, 0.42	-40.00, 100.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Eosinophils (GI/L)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	0.218 (0.0905)		0.208 (0.0915)		0.193 (0.1219)	
	95% CI	0.190, 0.250		0.170, 0.250		0.090, 0.290	
	Median	0.190		0.185		0.150	
	Q25, Q75	0.150, 0.270		0.145, 0.275		0.110, 0.300	
	Min, Max	0.09, 0.49		0.07, 0.43		0.04, 0.41	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Eosinophils (GI/L)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	32	32	9	9
	Mean (SD)	0.151 (0.0796)	-26.984 (34.5204)	0.153 (0.0651)	-22.013 (29.3060)	0.110 (0.0642)	-39.007 (17.3089)
	95% CI	0.120, 0.180	-37.120, -16.840	0.120, 0.180	-32.580, -11.440	0.060, 0.160	-52.320, -25.700
	Median	0.130	-33.333	0.150	-28.543	0.090	-43.333
	Q25, Q75	0.100, 0.180	-53.333, 0.000	0.110, 0.185	-42.463, -10.084	0.070, 0.160	-50.000, -40.000
	Min, Max	0.05, 0.37	-72.09, 77.78	0.03, 0.33	-57.14, 70.00	0.03, 0.23	-58.82, 0.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Basophils (GI/L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Mean (SD)	0.046 (0.0229)		0.047 (0.0212)		0.055 (0.0484)	
	95% CI	0.040, 0.060		0.040, 0.060		0.030, 0.080	
	Median	0.040		0.040		0.050	
	Q25, Q75	0.030, 0.060		0.030, 0.060		0.030, 0.060	
	Min, Max	0.01, 0.15		0.02, 0.10		0.01, 0.27	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Basophils (GI/L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	75	75	35	35	24	24
	Mean (SD)	0.045 (0.0186)	9.468 (51.0225)	0.053 (0.0229)	24.086 (52.7312)	0.045 (0.0187)	-0.446 (42.2563)
	95% CI	0.040, 0.050	-2.280, 21.210	0.040, 0.070	5.970, 42.200	0.030, 0.060	-18.290, 17.400
	Median	0.040	0.000	0.050	20.000	0.040	0.000
	Q25, Q75	0.030, 0.050	-20.000, 33.333	0.030, 0.060	-16.667, 50.000	0.030, 0.050	-29.167, 17.143
	Min, Max	0.01, 0.10	-83.33, 200.00	0.02, 0.12	-50.00, 175.00	0.02, 0.09	-66.67, 100.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set****Parameter (units): Basophils (GI/L)
Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34		13	
	Mean (SD)	0.050 (0.0254)		0.048 (0.0210)		0.045 (0.0171)	
	95% CI	0.040, 0.060		0.040, 0.060		0.030, 0.060	
	Median	0.045		0.045		0.050	
	Q25, Q75	0.030, 0.060		0.030, 0.060		0.030, 0.060	
	Min, Max	0.02, 0.15		0.02, 0.10		0.01, 0.07	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Basophils (GI/L)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	40	34	34	13	13
	Mean (SD)	0.046 (0.0239)	-3.805 (37.4013)	0.053 (0.0233)	28.357 (74.6320)	0.040 (0.0220)	6.960 (80.5573)
	95% CI	0.030, 0.060	-15.770, 8.160	0.040, 0.070	2.310, 54.400	0.020, 0.060	-41.730, 55.640
	Median	0.045	0.000	0.050	0.000	0.040	-16.667
	Q25, Q75	0.030, 0.065	-25.000, 24.286	0.030, 0.070	-25.000, 66.667	0.020, 0.050	-42.857, 0.000
	Min, Max	0.00, 0.11	-100.00, 66.67	0.02, 0.12	-50.00, 250.00	0.02, 0.10	-66.67, 200.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Basophils (GI/L)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35		12	
	Mean (SD)	0.049 (0.0253)		0.047 (0.0209)		0.046 (0.0162)	
	95% CI	0.040, 0.060		0.030, 0.060		0.030, 0.060	
	Median	0.040		0.040		0.050	
	Q25, Q75	0.030, 0.060		0.030, 0.060		0.035, 0.060	
	Min, Max	0.02, 0.15		0.02, 0.10		0.01, 0.06	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Basophils (GI/L)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	35	35	12	12
	Mean (SD)	0.054 (0.0439)	26.965 (140.9974)	0.046 (0.0195)	4.050 (34.7913)	0.043 (0.0226)	13.472 (82.5492)
	95% CI	0.030, 0.070	-18.750, 72.680	0.030, 0.060	-7.910, 16.010	0.020, 0.060	-38.980, 65.930
	Median	0.040	0.000	0.040	0.000	0.035	0.000
	Q25, Q75	0.030, 0.060	-25.000, 33.333	0.030, 0.060	-30.000, 25.000	0.030, 0.055	-41.667, 26.667
	Min, Max	0.02, 0.28	-44.44, 833.33	0.02, 0.10	-50.00, 75.00	0.02, 0.10	-66.67, 200.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set****Parameter (units): Basophils (GI/L)
Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	0.049 (0.0234)		0.048 (0.0211)		0.049 (0.0169)	
	95% CI	0.040, 0.060		0.030, 0.060		0.030, 0.070	
	Median	0.050		0.045		0.060	
	Q25, Q75	0.030, 0.060		0.030, 0.060		0.040, 0.060	
	Min, Max	0.02, 0.15		0.02, 0.10		0.01, 0.06	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Basophils (GI/L)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	32	32	9	9
	Mean (SD)	0.044 (0.0208)	-2.645 (46.4563)	0.048 (0.0247)	22.049 (93.2742)	0.031 (0.0176)	-10.926 (91.3141)
	95% CI	0.030, 0.050	-16.290, 11.000	0.030, 0.060	-11.590, 55.680	0.010, 0.050	-81.120, 59.270
	Median	0.040	0.000	0.040	0.000	0.030	-40.000
	Q25, Q75	0.030, 0.060	-33.333, 20.000	0.030, 0.060	-40.000, 41.667	0.020, 0.040	-66.667, -33.333
	Min, Max	0.01, 0.13	-73.33, 133.33	0.02, 0.12	-60.00, 300.00	0.01, 0.07	-83.33, 200.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set****Parameter (units): Platelets (GI/L)**
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Geometric Mean (CV%)	268.9 (24.39)		283.7 (23.78)		270.2 (33.02)	
	95% CI of Geometric Mean	254.4, 284.3		261.7, 307.6		235.8, 309.5	
	Median	260.0		290.0		252.5	
	Q25, Q75	231.0, 315.0		229.0, 330.0		224.5, 321.5	
	Min, Max	111, 482		187, 537		141, 563	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Platelets (GI/L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	75	75	35	35	24	24
	Geometric Mean (CV%)	276.6 (23.44)		279.1 (25.80)		268.6 (31.19)	
	95% CI of Geometric Mean	262.2, 291.8		255.7, 304.5		236.1, 305.5	
	Median	276.0	2.6	275.0	0.0	267.0	-1.7
	Q25, Q75	234.0, 315.0	-5.1, 10.9	231.0, 332.0	-6.1, 5.4	217.0, 318.5	-6.8, 11.2
	Min, Max	151, 466	-23, 36	184, 566	-25, 26	162, 545	-43, 55

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set****Parameter (units): Platelets (GI/L)
Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34		13	
	Geometric Mean (CV%)	271.4 (27.05)		281.4 (23.39)		263.0 (39.70)	
	95% CI of Geometric Mean	249.2, 295.5		259.5, 305.0		208.7, 331.4	
	Median	276.0		287.0		247.0	
	Q25, Q75	240.0, 323.0		229.0, 319.0		213.0, 296.0	
	Min, Max	111, 418		187, 537		141, 563	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Platelets (GI/L)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	40	40	34	34	13	13
	Geometric Mean (CV%)	274.5 (29.76)		264.7 (24.17)		256.5 (38.19)	
	95% CI of Geometric Mean	250.1, 301.4		243.6, 287.7		205.2, 320.6	
	Median	279.5	0.3	267.0	-5.8	224.0	-4.8
	Q25, Q75	231.5, 324.0	-9.5, 11.1	209.0, 302.0	-11.6, 0.3	193.0, 350.0	-9.3, 6.0
	Min, Max	118, 543	-24, 38	172, 442	-25, 19	160, 521	-24, 23

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set****Parameter (units): Platelets (GI/L)**
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35		12	
	Geometric Mean (CV%)	264.4 (24.92)		284.2 (23.82)		270.8 (40.86)	
	95% CI of Geometric Mean	244.2, 286.4		262.1, 308.1		210.9, 347.6	
	Median	266.0		290.0		262.0	
	Q25, Q75	235.0, 308.0		229.0, 330.0		207.0, 348.0	
	Min, Max	111, 395		187, 537		141, 563	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Platelets (GI/L)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	35	35	12	12
	Geometric Mean (CV%)	251.8 (25.91)		251.3 (22.31)		246.9 (37.85)	
	95% CI of Geometric Mean	231.8, 273.5		232.9, 271.1		195.6, 311.5	
	Median	249.0	-4.1	246.0	-12.0	234.0	-6.3
	Q25, Q75	207.0, 305.0	-12.0, 3.8	211.0, 277.0	-19.7, -5.2	192.5, 315.0	-13.8, -2.0
	Min, Max	128, 410	-28, 24	167, 421	-33, 17	133, 489	-31, 6

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set**

Parameter (units): Platelets (GI/L)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Geometric Mean (CV%)	265.4 (24.34)		291.9 (22.93)		290.0 (44.55)	
	95% CI of Geometric Mean	247.3, 284.8		269.0, 316.8		209.1, 402.3	
	Median	266.0		292.0		269.0	
	Q25, Q75	226.0, 308.0		253.0, 335.5		230.0, 400.0	
	Min, Max	111, 395		187, 537		141, 563	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.1 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - PP Set

Parameter (units): Platelets (GI/L)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	32	32	9	9
	Geometric Mean (CV%)	238.0 (30.62)		253.3 (29.17)		254.2 (43.34)	
	95% CI of Geometric Mean	218.0, 260.0		228.5, 280.9		184.7, 349.7	
	Median	242.0	-9.7	250.5	-13.0	248.0	-7.4
	Q25, Q75	198.0, 283.0	-16.2, -1.2	212.0, 273.5	-21.9, -6.5	211.0, 359.0	-19.9, -2.8
	Min, Max	93, 443	-47, 32	164, 713	-35, 33	137, 451	-39, 2

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS****Parameter (units): Leukocytes (GI/L)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41		39	
	Mean (SD)	7.760 (1.7660)		8.350 (1.8776)		7.926 (2.3281)	
	95% CI	7.360, 8.160		7.750, 8.950		7.170, 8.690	
	Median	7.535		8.010		7.430	
	Q25, Q75	6.660, 8.710		6.800, 9.930		6.110, 9.900	
	Min, Max	3.91, 13.07		5.13, 11.97		3.59, 13.55	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Leukocytes (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	80	80	41	41	39	39
	Mean (SD)	7.409 (1.8105)	-3.623 (16.6750)	8.293 (1.7891)	0.434 (14.0076)	7.188 (1.7830)	-7.385 (13.3471)
	95% CI	7.000, 7.820	-7.340, 0.090	7.720, 8.860	-3.990, 4.860	6.600, 7.770	-11.720, -3.050
	Median	7.385	-6.238	8.350	1.322	7.050	-6.424
	Q25, Q75	6.175, 8.560	-13.927, 7.679	6.690, 9.410	-7.590, 8.453	6.080, 8.110	-17.819, 1.506
	Min, Max	3.91, 11.90	-45.52, 45.66	5.16, 11.54	-38.46, 30.12	3.31, 11.78	-36.02, 22.88

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Leukocytes (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	80	80	41	41	39	39
	Mean (SD)	7.002 (1.6963)	-8.702 (15.2885)	7.820 (1.8227)	-5.123 (15.6599)	7.134 (2.0604)	-8.221 (17.0878)
	95% CI	6.620, 7.380	-12.110, -5.290	7.240, 8.400	-10.070, -0.180	6.460, 7.810	-13.770, -2.680
	Median	6.615	-10.016	7.570	-4.793	6.770	-9.227
	Q25, Q75	5.940, 7.645	-19.079, -1.150	6.390, 8.900	-16.009, 5.724	5.420, 8.080	-22.283, 3.365
	Min, Max	3.45, 11.35	-57.09, 38.38	4.73, 12.45	-41.32, 33.03	3.50, 11.78	-40.52, 33.89

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Leukocytes (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	80	80	41	41	39	39
	Mean (SD)	6.927 (1.8298)	-9.932 (16.9361)	7.580 (1.6286)	-7.965 (14.2287)	6.958 (1.8526)	-10.432 (14.1685)
	95% CI	6.510, 7.340	-13.710, -6.160	7.060, 8.100	-12.460, -3.470	6.350, 7.560	-15.030, -5.830
	Median	6.830	-11.724	7.760	-8.052	6.770	-8.293
	Q25, Q75	5.555, 8.020	-21.524, 1.943	6.260, 8.450	-17.561, 5.049	5.600, 7.920	-21.162, 1.449
	Min, Max	4.01, 11.71	-47.89, 34.43	4.82, 10.45	-35.40, 18.16	3.21, 11.78	-42.96, 19.09

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Leukocytes (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	80	80	41	41	39	39
	Mean (SD)	6.871 (1.6596)	-9.664 (19.4726)	7.483 (2.1081)	-9.631 (18.9636)	7.274 (2.4649)	-7.519 (17.3413)
	95% CI	6.500, 7.250	-14.000, -5.330	6.810, 8.150	-15.620, -3.640	6.470, 8.080	-13.150, -1.890
	Median	6.470	-10.967	6.920	-11.847	6.770	-9.749
	Q25, Q75	5.725, 8.095	-23.408, 2.567	6.150, 9.370	-21.795, 0.000	5.540, 8.600	-20.579, 0.000
	Min, Max	3.60, 10.69	-55.22, 53.29	4.47, 12.98	-40.45, 37.86	3.24, 16.72	-32.46, 43.03

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS****Parameter (units): Neutrophils (GI/L)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41		39	
	Mean (SD)	4.393 (1.4203)		4.687 (1.4975)		4.497 (1.7611)	
	95% CI	4.070, 4.710		4.210, 5.160		3.920, 5.070	
	Median	4.315		4.490		4.350	
	Q25, Q75	3.430, 5.155		3.630, 5.950		3.030, 5.470	
	Min, Max	1.25, 8.64		2.48, 8.11		1.39, 10.01	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Neutrophils (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	80	80	41	41	39	39
	Mean (SD)	4.147 (1.4119)	-3.890 (24.7244)	4.623 (1.3851)	1.277 (20.4363)	3.943 (1.3998)	-9.933 (19.9411)
	95% CI	3.830, 4.470	-9.400, 1.620	4.180, 5.070	-5.180, 7.730	3.480, 4.400	-16.400, -3.460
	Median	4.145	-9.260	4.780	-0.254	3.920	-10.687
	Q25, Q75	3.220, 5.140	-19.300, 7.044	3.410, 5.550	-12.939, 16.894	3.010, 4.700	-22.737, 1.689
	Min, Max	1.30, 7.48	-58.70, 90.35	2.41, 7.18	-54.38, 39.37	1.02, 7.78	-54.26, 49.32

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS****Parameter (units): Neutrophils (GI/L)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	80	80	41	41	39	39
	Mean (SD)	3.853 (1.4115)	-11.205 (20.8889)	4.362 (1.4878)	-3.655 (25.7420)	3.837 (1.4751)	-11.257 (23.8830)
	95% CI	3.530, 4.170	-15.860, -6.550	3.890, 4.840	-11.780, 4.480	3.350, 4.320	-19.000, -3.510
	Median	3.655	-14.193	4.150	-1.875	3.500	-12.639
	Q25, Q75	2.945, 4.750	-23.749, -3.524	3.050, 5.070	-21.451, 13.536	2.670, 4.530	-28.383, 0.000
	Min, Max	1.02, 7.94	-78.62, 55.64	2.35, 8.22	-56.97, 62.28	1.38, 7.88	-52.45, 64.89

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Neutrophils (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	80	80	41	41	39	39
	Mean (SD)	3.810 (1.4211)	-11.777 (24.1796)	4.198 (1.2804)	-7.475 (21.8378)	3.704 (1.3492)	-14.260 (20.4873)
	95% CI	3.490, 4.130	-17.160, -6.390	3.790, 4.610	-14.370, -0.580	3.260, 4.150	-20.910, -7.610
	Median	3.610	-13.149	4.250	-9.530	3.500	-15.261
	Q25, Q75	2.795, 4.740	-25.428, -2.628	3.370, 4.950	-23.742, 14.141	2.550, 4.510	-28.319, 0.000
	Min, Max	1.33, 8.54	-68.55, 105.78	1.85, 7.50	-56.78, 26.13	1.36, 7.58	-64.31, 25.57

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Neutrophils (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	80	80	41	41	39	39
	Mean (SD)	4.120 (1.3492)	-2.057 (30.4790)	4.564 (1.6279)	0.435 (29.6439)	4.284 (1.8994)	-1.442 (30.5530)
	95% CI	3.810, 4.420	-8.840, 4.730	4.050, 5.080	-8.930, 9.800	3.660, 4.900	-11.350, 8.470
	Median	4.000	-6.402	4.260	-6.743	4.020	-4.063
	Q25, Q75	3.220, 4.990	-23.782, 16.817	3.280, 5.360	-22.039, 14.000	2.900, 4.910	-23.678, 8.333
	Min, Max	1.26, 7.71	-73.59, 105.60	1.98, 8.73	-44.79, 72.71	1.74, 12.51	-41.06, 95.78

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS****Parameter (units): Lymphocytes (GI/L)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41		39	
	Mean (SD)	2.693 (0.7400)		2.923 (0.6720)		2.740 (0.7395)	
	95% CI	2.520, 2.860		2.710, 3.140		2.490, 2.980	
	Median	2.550		2.840		2.620	
	Q25, Q75	2.170, 3.155		2.450, 3.330		2.180, 3.430	
	Min, Max	1.24, 5.16		1.33, 4.40		1.17, 4.14	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Lymphocytes (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	80	80	41	41	39	39
	Mean (SD)	2.586 (0.6825)	-2.214 (17.4755)	2.915 (0.6225)	1.160 (15.4575)	2.568 (0.6390)	-4.369 (15.2731)
	95% CI	2.430, 2.740	-6.110, 1.680	2.710, 3.120	-3.720, 6.040	2.360, 2.780	-9.330, 0.590
	Median	2.460	-4.289	2.940	-0.400	2.500	-5.970
	Q25, Q75	2.045, 2.995	-12.856, 7.185	2.470, 3.320	-10.942, 7.738	2.080, 2.950	-12.876, 2.809
	Min, Max	1.26, 4.21	-39.49, 55.17	1.74, 4.33	-21.32, 45.11	1.53, 3.97	-31.97, 37.61

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Lymphocytes (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	80	80	41	41	39	39
	Mean (SD)	2.496 (0.6838)	-5.927 (16.7509)	2.724 (0.7066)	-5.047 (20.6195)	2.661 (0.7154)	-0.895 (20.0269)
	95% CI	2.340, 2.650	-9.660, -2.190	2.500, 2.950	-11.560, 1.470	2.420, 2.900	-7.390, 5.600
	Median	2.370	-5.483	2.740	-2.469	2.690	-2.290
	Q25, Q75	1.955, 2.820	-18.199, 2.975	2.170, 3.160	-19.392, 10.963	2.050, 3.180	-11.667, 3.636
	Min, Max	1.23, 4.17	-43.48, 42.27	1.59, 4.63	-50.31, 49.62	1.53, 4.56	-36.40, 75.21

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Lymphocytes (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	80	80	41	41	39	39
	Mean (SD)	2.480 (0.7085)	-6.257 (19.3238)	2.712 (0.6015)	-5.546 (16.6528)	2.636 (0.7095)	-2.329 (15.3141)
	95% CI	2.320, 2.640	-10.560, -1.950	2.520, 2.910	-10.810, -0.280	2.400, 2.870	-7.300, 2.640
	Median	2.370	-4.524	2.690	-6.250	2.500	0.000
	Q25, Q75	1.940, 2.915	-16.302, 4.315	2.230, 3.230	-13.070, 0.802	2.220, 3.130	-11.651, 9.913
	Min, Max	0.92, 4.23	-51.71, 58.08	1.59, 4.15	-50.31, 45.87	1.48, 4.39	-39.46, 26.50

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Lymphocytes (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	80	80	41	41	39	39
	Mean (SD)	2.156 (0.6177)	-17.926 (19.1451)	2.251 (0.6252)	-21.809 (18.5731)	2.372 (0.6455)	-11.494 (19.5004)
	95% CI	2.010, 2.300	-22.190, -13.660	2.050, 2.450	-27.680, -15.940	2.160, 2.590	-17.820, -5.170
	Median	2.045	-20.969	2.110	-25.899	2.420	-14.184
	Q25, Q75	1.730, 2.450	-31.741, -4.242	1.770, 2.510	-32.524, -15.775	1.930, 2.910	-27.114, 0.321
	Min, Max	0.92, 3.92	-52.70, 23.95	1.19, 3.50	-50.31, 42.86	1.30, 3.83	-41.84, 44.44

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS****Parameter (units): Monocytes (GI/L)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41		39	
	Mean (SD)	0.415 (0.1174)		0.452 (0.1561)		0.415 (0.1425)	
	95% CI	0.380, 0.450		0.400, 0.510		0.360, 0.470	
	Median	0.400		0.420		0.390	
	Q25, Q75	0.330, 0.485		0.350, 0.560		0.290, 0.500	
	Min, Max	0.18, 0.79		0.18, 0.80		0.18, 0.75	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Monocytes (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	80	80	41	41	39	39
	Mean (SD)	0.445 (0.1147)	10.802 (25.0477)	0.465 (0.1319)	7.883 (25.4042)	0.431 (0.1523)	6.638 (25.6660)
	95% CI	0.410, 0.480	5.220, 16.380	0.420, 0.510	-0.140, 15.910	0.380, 0.490	-1.690, 14.960
	Median	0.445	11.270	0.490	10.714	0.390	0.000
	Q25, Q75	0.370, 0.515	-5.584, 29.752	0.340, 0.560	-3.125, 21.739	0.310, 0.510	-11.594, 22.222
	Min, Max	0.20, 0.80	-59.70, 75.76	0.20, 0.75	-63.24, 85.71	0.22, 0.83	-28.26, 72.73

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Monocytes (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	80	80	41	41	39	39
	Mean (SD)	0.419 (0.1423)	3.081 (26.1687)	0.452 (0.1335)	5.013 (28.6970)	0.403 (0.1448)	-0.128 (26.6244)
	95% CI	0.380, 0.460	-2.750, 8.910	0.410, 0.500	-4.050, 14.080	0.350, 0.450	-8.760, 8.510
	Median	0.400	-0.909	0.430	2.941	0.400	0.000
	Q25, Q75	0.360, 0.475	-15.038, 17.546	0.350, 0.550	-15.000, 19.231	0.300, 0.500	-18.919, 11.111
	Min, Max	0.18, 1.03	-47.76, 88.46	0.20, 0.73	-34.88, 116.67	0.20, 0.75	-41.46, 76.67

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Monocytes (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	80	80	41	41	39	39
	Mean (SD)	0.415 (0.1460)	3.810 (37.0050)	0.412 (0.1417)	-4.535 (27.6654)	0.390 (0.1621)	-4.444 (27.3587)
	95% CI	0.380, 0.450	-4.430, 12.050	0.360, 0.460	-13.270, 4.200	0.330, 0.450	-13.320, 4.430
	Median	0.400	-0.633	0.370	-12.963	0.370	-8.333
	Q25, Q75	0.310, 0.505	-18.231, 20.938	0.300, 0.480	-26.230, 19.231	0.270, 0.470	-24.138, 18.919
	Min, Max	0.12, 0.83	-68.66, 124.32	0.21, 0.73	-69.12, 72.22	0.10, 0.92	-62.96, 58.62

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Monocytes (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	80	80	41	41	39	39
	Mean (SD)	0.402 (0.1629)	-1.154 (32.4590)	0.426 (0.1440)	-1.485 (30.3414)	0.412 (0.1955)	1.144 (40.1577)
	95% CI	0.360, 0.440	-8.380, 6.070	0.380, 0.480	-11.070, 8.100	0.340, 0.480	-11.880, 14.170
	Median	0.375	-4.396	0.410	-8.333	0.380	-4.878
	Q25, Q75	0.280, 0.470	-21.320, 15.472	0.330, 0.510	-20.833, 15.790	0.260, 0.520	-27.273, 23.684
	Min, Max	0.19, 0.98	-60.61, 102.78	0.20, 0.86	-52.56, 120.51	0.07, 0.93	-74.07, 120.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS****Parameter (units): Eosinophils (GI/L)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41		39	
	Mean (SD)	0.214 (0.1061)		0.240 (0.1356)		0.223 (0.1552)	
	95% CI	0.180, 0.240		0.190, 0.290		0.170, 0.280	
	Median	0.190		0.190		0.170	
	Q25, Q75	0.140, 0.270		0.160, 0.300		0.110, 0.310	
	Min, Max	0.04, 0.67		0.07, 0.74		0.03, 0.77	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Eosinophils (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	80	80	41	41	39	39
	Mean (SD)	0.187 (0.0955)	-8.139 (27.2188)	0.240 (0.1561)	2.687 (28.7041)	0.197 (0.1391)	2.341 (59.7068)
	95% CI	0.160, 0.210	-14.200, -2.080	0.190, 0.290	-6.380, 11.750	0.150, 0.250	-17.020, 21.700
	Median	0.170	-11.438	0.220	-5.556	0.150	-9.091
	Q25, Q75	0.120, 0.220	-28.139, 6.667	0.160, 0.280	-17.647, 21.053	0.100, 0.280	-23.529, 0.000
	Min, Max	0.07, 0.51	-58.82, 100.00	0.06, 1.03	-36.84, 90.00	0.05, 0.66	-76.92, 200.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Eosinophils (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	80	80	41	41	39	39
	Mean (SD)	0.189 (0.0872)	-4.193 (38.1020)	0.229 (0.1196)	0.437 (33.7830)	0.188 (0.1071)	0.310 (51.7174)
	95% CI	0.160, 0.210	-12.680, 4.290	0.190, 0.270	-10.230, 11.110	0.150, 0.230	-16.460, 17.080
	Median	0.180	-11.882	0.210	-7.692	0.160	-9.091
	Q25, Q75	0.120, 0.250	-30.536, 11.111	0.130, 0.290	-25.000, 11.765	0.100, 0.250	-33.333, 15.385
	Min, Max	0.06, 0.48	-60.00, 120.00	0.05, 0.64	-55.81, 105.26	0.04, 0.52	-61.54, 166.67

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Eosinophils (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	80	80	41	41	39	39
	Mean (SD)	0.175 (0.1042)	-12.668 (38.0421)	0.211 (0.1347)	-9.330 (39.3744)	0.183 (0.1037)	-4.915 (41.1881)
	95% CI	0.150, 0.200	-21.140, -4.200	0.160, 0.260	-21.760, 3.100	0.140, 0.220	-18.270, 8.440
	Median	0.155	-19.091	0.170	-15.790	0.160	-9.091
	Q25, Q75	0.100, 0.215	-37.088, 0.000	0.130, 0.280	-28.571, 0.000	0.100, 0.240	-34.483, 4.348
	Min, Max	0.05, 0.68	-73.08, 125.00	0.05, 0.60	-70.00, 140.00	0.05, 0.47	-69.23, 114.29

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Eosinophils (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	80	80	41	41	39	39
	Mean (SD)	0.152 (0.0887)	-23.748 (35.8004)	0.193 (0.1199)	-16.755 (32.9414)	0.164 (0.1044)	-12.053 (84.8005)
	95% CI	0.130, 0.180	-31.720, -15.780	0.150, 0.240	-27.160, -6.350	0.130, 0.200	-39.550, 15.440
	Median	0.120	-31.174	0.160	-22.222	0.150	-25.000
	Q25, Q75	0.090, 0.180	-47.604, 0.000	0.120, 0.210	-38.235, -4.255	0.080, 0.220	-43.902, 0.000
	Min, Max	0.02, 0.42	-85.71, 86.67	0.03, 0.60	-57.14, 105.26	0.00, 0.45	-100.00, 471.43

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS****Parameter (units): Basophils (GI/L)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41		39	
	Mean (SD)	0.046 (0.0230)		0.048 (0.0205)		0.052 (0.0404)	
	95% CI	0.040, 0.060		0.040, 0.060		0.030, 0.070	
	Median	0.040		0.050		0.040	
	Q25, Q75	0.030, 0.060		0.030, 0.060		0.030, 0.060	
	Min, Max	0.01, 0.15		0.02, 0.10		0.01, 0.27	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Basophils (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	80	80	41	41	39	39
	Mean (SD)	0.045 (0.0196)	10.793 (52.6383)	0.053 (0.0219)	20.503 (49.9393)	0.049 (0.0311)	12.653 (98.3676)
	95% CI	0.040, 0.050	-0.930, 22.510	0.040, 0.060	4.740, 36.270	0.030, 0.060	-19.240, 44.540
	Median	0.040	0.000	0.050	20.000	0.040	0.000
	Q25, Q75	0.030, 0.050	-20.000, 33.333	0.040, 0.060	-16.667, 50.000	0.030, 0.060	-25.000, 25.000
	Min, Max	0.01, 0.11	-83.33, 200.00	0.02, 0.12	-50.00, 175.00	0.02, 0.20	-66.67, 566.67

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Basophils (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	80	80	41	41	39	39
	Mean (SD)	0.047 (0.0225)	9.936 (47.4226)	0.053 (0.0243)	26.129 (70.2661)	0.044 (0.0230)	1.769 (57.6868)
	95% CI	0.040, 0.060	-0.620, 20.490	0.040, 0.070	3.940, 48.310	0.030, 0.060	-16.940, 20.470
	Median	0.050	0.000	0.050	0.000	0.040	0.000
	Q25, Q75	0.030, 0.060	-20.000, 33.333	0.040, 0.070	-20.000, 60.000	0.030, 0.050	-33.333, 0.000
	Min, Max	0.00, 0.11	-100.00, 150.00	0.02, 0.12	-50.00, 250.00	0.02, 0.13	-81.48, 200.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Basophils (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	80	80	41	41	39	39
	Mean (SD)	0.049 (0.0352)	18.633 (104.6507)	0.047 (0.0188)	4.386 (33.3669)	0.045 (0.0218)	5.686 (66.2108)
	95% CI	0.040, 0.060	-4.660, 41.930	0.040, 0.060	-6.150, 14.920	0.030, 0.060	-15.780, 27.150
	Median	0.040	0.000	0.040	0.000	0.040	0.000
	Q25, Q75	0.030, 0.060	-26.786, 36.667	0.030, 0.060	-25.000, 25.000	0.030, 0.060	-33.333, 20.000
	Min, Max	0.00, 0.28	-100.00, 833.33	0.02, 0.10	-50.00, 75.00	0.02, 0.10	-77.78, 233.33

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Basophils (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	80	80	41	41	39	39
	Mean (SD)	0.043 (0.0200)	4.033 (49.6430)	0.050 (0.0244)	20.809 (83.1902)	0.042 (0.0232)	-7.183 (55.1645)
	95% CI	0.030, 0.050	-7.020, 15.090	0.040, 0.060	-5.450, 47.070	0.030, 0.050	-25.070, 10.700
	Median	0.040	0.000	0.040	0.000	0.040	-12.500
	Q25, Q75	0.030, 0.050	-33.333, 33.333	0.030, 0.060	-33.333, 33.333	0.030, 0.050	-33.333, 0.000
	Min, Max	0.01, 0.13	-75.00, 150.00	0.02, 0.12	-60.00, 300.00	0.00, 0.09	-100.00, 200.00

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Platelets (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41		39	
	Geometric Mean (CV%)	267.8 (23.99)		283.1 (22.87)		275.5 (29.27)	
	95% CI of Geometric Mean	254.0, 282.3		263.6, 304.1		251.0, 302.3	
	Median	257.0		290.0		269.0	
	Q25, Q75	230.0, 315.0		239.0, 319.0		230.0, 318.0	
	Min, Max	111, 482		187, 537		141, 563	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Platelets (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	80	80	41	41	39	39
	Geometric Mean (CV%)	274.9 (23.20)	0	281.7 (25.68)	0	268.5 (27.16)	0
	95% CI of Geometric Mean	261.2, 289.3		260.1, 305.2		246.2, 292.8	
	Median	273.0	1.4	278.0	1.4	278.0	-3.1
	Q25, Q75	234.0, 314.5	-5.1, 10.6	232.0, 324.0	-4.4, 4.5	217.0, 317.0	-8.5, 5.6
	Min, Max	151, 466	-23, 36	184, 566	-25, 37	162, 545	-43, 55

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Platelets (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	80	80	41	41	39	39
	Geometric Mean (CV%)	270.2 (25.54)	0	266.3 (22.88)	0	265.5 (28.55)	0
	95% CI of Geometric Mean	255.4, 285.8		247.9, 286.0		242.5, 290.8	
	Median	263.5	1.7	271.0	-5.5	258.0	-4.0
	Q25, Q75	232.5, 318.5	-7.7, 10.6	220.0, 302.0	-11.6, 0.3	213.0, 320.0	-10.4, 3.8
	Min, Max	118, 543	-28, 38	172, 442	-25, 19	160, 522	-32, 53

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Platelets (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	80	80	41	41	39	39
	Geometric Mean (CV%)	252.7 (23.10)	0	251.6 (21.50)	0	254.5 (27.15)	0
	95% CI of Geometric Mean	240.2, 265.9		235.2, 269.1		233.4, 277.6	
	Median	247.0	-4.6	248.0	-11.9	248.0	-5.3
	Q25, Q75	219.5, 294.5	-12.3, 3.5	213.0, 277.0	-19.1, -5.2	218.0, 313.0	-12.0, 0.0
	Min, Max	128, 410	-35, 24	167, 421	-33, 17	133, 489	-48, 54

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.



Tables 15.2.4.31.2 Descriptive Statistics of Total WBC Counts (GI/L), Neutrophils Counts (GI/L), Basophils Counts (GI/L), Eosinophils Counts (GI/L), Lymphocytes Counts (GI/L), Monocytes Counts (GI/L) and Platelet Counts (GI/L) - FAS

Parameter (units): Platelets (GI/L)

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	80	80	41	41	39	39
	Geometric Mean (CV%)	242.8 (27.19)	0	249.4 (26.91)	0	255.1 (29.03)	0
	95% CI of Geometric Mean	228.8, 257.8		229.3, 271.1		232.6, 279.8	
	Median	246.0	-7.7	249.0	-11.9	263.0	-6.7
	Q25, Q75	213.0, 282.5	-15.8, -0.2	207.0, 272.0	-20.1, -4.8	211.0, 306.0	-14.1, 1.2
	Min, Max	93, 443	-47, 32	164, 713	-35, 33	137, 451	-43, 53

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Product Use Time Period: Period 1**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Prostaglandin F2 Alpha (pg/mg creat)	Baseline	n	69		34		21	
		Missing, n(%)	6 (8.0)		1 (2.9)		3 (12.5)	
		Geometric Mean (CV%)	249.1 (34.74)		276.4 (52.13)		272.4 (57.67)	
		95% CI of Geometric Mean	229.6, 270.2		232.9, 328.1		213.4, 347.7	
		Median	252.9		283.2		258.3	
		Q25, Q75	196.4, 319.1		185.1, 395.7		170.3, 404.9	
		Min, Max	120, 513		96, 851		117, 694	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the

Note: last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Product Use Time Period: Period 1**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Prostaglandin F2 Alpha (pg/mg creat)	Day 5	n	73	69	34	34	22	21
		Missing, n(%)	2 (2.7)	6 (8.0)	1 (2.9)	1 (2.9)	2 (8.3)	3 (12.5)
		Geometric Mean (CV%)	217.5 (34.50)		275.7 (46.67)		240.6 (61.11)	
		95% CI of Geometric Mean	201.1, 235.3		236.1, 321.9		187.4, 308.9	
		Median	213.3	-10.5	269.4	-4.1	222.3	-8.9
		Q25, Q75	176.8, 260.0	-22.6, 1.1	193.1, 394.7	-9.4, 7.7	154.8, 390.4	-19.0, -1.9
		Min, Max	106, 500	-55, 42	111, 714	-37, 116	101, 731	-50, 129

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the

Note: last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Prostaglandin F2 Alpha (pg/mg creat)	Baseline	n	39		33		12	
		Missing, n(%)	1 (2.5)		1 (2.9)		1 (7.7)	
		Geometric Mean (CV%)	237.3 (35.31)		268.6 (53.69)		314.2 (56.94)	
		95% CI of Geometric Mean	212.3, 265.2		224.6, 321.1		224.3, 440.0	
		Median	237.6		264.6		336.5	
		Q25, Q75	192.7, 288.2		181.3, 387.5		199.5, 481.4	
		Min, Max	120, 513		96, 851		144, 694	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the

Note: last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Prostaglandin F2 Alpha (pg/mg creat)	Day 30	n	40	39	33	33	13	12
		Missing, n(%)	0	1 (2.5)	1 (2.9)	1 (2.9)	0	1 (7.7)
		Geometric Mean (CV%)	261.4 (35.43)		316.6 (59.30)		328.7 (64.26)	
		95% CI of Geometric Mean	234.1, 291.9		260.5, 384.6		230.4, 468.9	
		Median	263.1	8.4	290.9	17.6	312.3	0.6
		Q25, Q75	200.6, 338.8	-1.0, 24.9	207.5, 472.0	2.3, 35.4	237.2, 504.6	-23.9, 31.2
		Min, Max	128, 600	-56, 124	112, 1140	-46, 204	101, 865	-30, 196

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the

Note: last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Prostaglandin F2 Alpha (pg/mg creat)	Baseline	n	37		34		11	
		Missing, n(%)	2 (5.1)		1 (2.9)		1 (8.3)	
		Geometric Mean (CV%)	246.0 (31.53)		269.0 (52.77)		273.2 (58.94)	
		95% CI of Geometric Mean	221.9, 272.6		226.2, 319.8		189.3, 394.3	
		Median	244.6		273.3		241.6	
		Q25, Q75	201.4, 282.4		181.3, 387.5		160.4, 458.6	
		Min, Max	128, 513		96, 851		144, 694	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the

Note: last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Prostaglandin F2 Alpha (pg/mg creat)	Day 60	n	39	37	34	34	11	11
		Missing, n(%)	0	2 (5.1)	1 (2.9)	1 (2.9)	1 (8.3)	1 (8.3)
		Geometric Mean (CV%)	263.2 (37.24)		309.6 (61.17)		276.0 (70.16)	
		95% CI of Geometric Mean	234.1, 295.8		254.2, 376.9		180.4, 422.2	
		Median	262.6	6.5	290.1	8.0	300.8	6.0
		Q25, Q75	204.4, 307.8	-7.6, 32.0	199.2, 465.0	-5.9, 32.7	170.0, 452.8	-20.8, 31.6
		Min, Max	140, 601	-54, 97	130, 1063	-32, 124	95, 659	-37, 65

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the

Note: last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Prostaglandin F2 Alpha (pg/mg creat)	Baseline	n	45		32		9	
		Missing, n(%)	2 (4.3)		0		0	
		Geometric Mean (CV%)	244.3 (32.26)		276.3 (52.87)		270.8 (58.03)	
		95% CI of Geometric Mean	222.2, 268.5		231.0, 330.6		178.9, 409.7	
		Median	244.6		283.2		241.6	
		Q25, Q75	196.8, 288.2		183.2, 398.1		170.3, 404.9	
		Min, Max	128, 513		96, 851		144, 694	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the

Note: last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
Prostaglandin F2 Alpha (pg/mg creat)	Day 90	n	47	45	32	32	9	9
		Missing, n(%)	0	2 (4.3)	0	0	0	0
		Geometric Mean (CV%)	251.6 (34.57)		317.2 (52.89)		281.0 (49.97)	
		95% CI of Geometric Mean	227.9, 277.7		265.1, 379.4		195.5, 404.0	
		Median	256.4	1.4	340.0	12.9	307.8	-1.5
		Q25, Q75	193.0, 316.2	-14.0, 22.3	203.9, 418.8	0.7, 28.6	197.7, 424.0	-20.1, 18.7
		Min, Max	140, 568	-47, 72	151, 1158	-31, 119	149, 525	-32, 149

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the

Note: last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Product Use Time Period: Period 1**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Baseline	n	69		34		21	
		Missing, n(%)	6 (8.0)		1 (2.9)		3 (12.5)	
		Geometric Mean (CV%)	576.5 (51.54)		592.6 (46.12)		550.0 (37.95)	
		95% CI of Geometric Mean	513.0, 647.8		508.4, 690.8		465.4, 650.0	
		Median	639.3		590.2		538.6	
		Q25, Q75	400.5, 796.8		400.0, 789.3		452.8, 680.5	
		Min, Max	146, 2066		241, 1440		270, 1058	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the

Note: last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Product Use Time Period: Period 1**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Day 5	n	73	69	34	34	22	21
		Missing, n(%)	2 (2.7)	6 (8.0)	1 (2.9)	1 (2.9)	2 (8.3)	3 (12.5)
		Geometric Mean (CV%)	522.4 (44.20)		638.8 (38.60)		499.3 (40.12)	
		95% CI of Geometric Mean	473.3, 576.5		560.9, 727.6		420.6, 592.6	
		Median	545.1	-10.4	640.8	0.9	510.6	-8.3
		Q25, Q75	366.8, 683.3	-23.1, -0.1	495.1, 835.4	-12.0, 20.4	409.9, 575.3	-18.4, 2.5
		Min, Max	223, 1542	-67, 166	325, 1349	-37, 203	200, 1027	-58, 33

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the

Note: last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Baseline	n	39		33		12	
		Missing, n(%)	1 (2.5)		1 (2.9)		1 (7.7)	
		Geometric Mean (CV%)	610.5 (51.71)		594.1 (40.57)		563.5 (46.62)	
		95% CI of Geometric Mean	521.3, 714.9		517.3, 682.3		425.0, 746.9	
		Median	647.4		594.7		584.0	
		Q25, Q75	461.0, 797.4		434.8, 762.6		387.2, 829.0	
		Min, Max	146, 2066		330, 1440		270, 1056	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the

Note: last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Day 30	n	40	39	33	33	13	12
		Missing, n(%)	0	1 (2.5)	1 (2.9)	1 (2.9)	0	1 (7.7)
		Geometric Mean (CV%)	409.6 (55.38)		453.2 (59.10)		407.3 (46.61)	
		95% CI of Geometric Mean	347.1, 483.3		373.2, 550.3		311.5, 532.5	
		Median	452.2	-25.2	497.3	-19.4	390.6	-27.1
		Q25, Q75	329.8, 567.5	-47.4, -11.1	393.0, 632.2	-34.9, 3.2	348.8, 560.6	-41.2, -13.8
		Min, Max	78, 1058	-81, 101	93, 1080	-85, 62	180, 851	-65, 7

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the

Note: last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Baseline	n	37		34		11	
		Missing, n(%)	2 (5.1)		1 (2.9)		1 (8.3)	
		Geometric Mean (CV%)	632.5 (45.07)		578.5 (43.28)		552.1 (43.56)	
		95% CI of Geometric Mean	548.0, 730.0		500.6, 668.6		417.2, 730.5	
		Median	658.9		584.7		553.8	
		Q25, Q75	467.2, 794.7		400.0, 762.6		375.0, 680.5	
		Min, Max	277, 2066		241, 1440		270, 1056	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the

Note: last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Day 60	n	39	37	34	34	11	11
		Missing, n(%)	0	2 (5.1)	1 (2.9)	1 (2.9)	1 (8.3)	1 (8.3)
		Geometric Mean (CV%)	446.3 (62.33)		424.7 (66.44)		297.4 (117.39)	
		95% CI of Geometric Mean	370.6, 537.4		343.8, 524.5		159.1, 555.8	
		Median	508.8	-23.0	482.1	-15.7	489.5	-20.5
		Q25, Q75	370.3, 620.3	-44.9, 3.0	289.7, 628.5	-39.9, -1.8	109.3, 585.9	-74.8, -13.9
		Min, Max	72, 1230	-89, 159	85, 1414	-85, 62	70, 844	-81, 54

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the

Note: last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Baseline	n	45		32		9	
		Missing, n(%)	2 (4.3)		0		0	
		Geometric Mean (CV%)	611.9 (48.66)		575.6 (44.39)		518.1 (42.83)	
		95% CI of Geometric Mean	532.7, 702.9		494.0, 670.8		377.9, 710.2	
		Median	647.4		584.7		553.8	
		Q25, Q75	467.2, 796.0		399.1, 770.4		375.0, 643.9	
		Min, Max	146, 2066		241, 1440		270, 1056	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the

Note: last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Day 90	n	47	45	32	32	9	9
		Missing, n(%)	0	2 (4.3)	0	0	0	0
		Geometric Mean (CV%)	421.4 (66.64)		438.2 (65.79)		372.1 (72.81)	
		95% CI of Geometric Mean	352.7, 503.5		353.0, 544.1		225.4, 614.4	
		Median	471.8	-22.0	531.1	-14.2	501.3	-22.1
		Q25, Q75	350.7, 601.2	-36.3, -6.7	350.7, 607.5	-42.1, 4.6	281.4, 552.4	-31.7, -12.0
		Min, Max	74, 1243	-88, 70	64, 1250	-83, 142	121, 721	-75, 54

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the

Note: last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1.1 Descriptive Statistics of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set****Product Use Time Period: Period 1**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
			Raw value	%	Raw value	%	Raw value	%
				Change(*)		Change(*)		Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Baseline	n	69		34		21	
		Missing, n(%)	6 (8.0)		1 (2.9)		3 (12.5)	
		Geometric Mean (CV%)	576.5 (51.54)		592.6 (46.12)		550.0 (37.95)	
		95% CI of Geometric Mean	513.0, 647.8		508.4, 690.8		465.4, 650.0	
		Median	639.3		590.2		538.6	
		Q25, Q75	400.5, 796.8		400.0, 789.3		452.8, 680.5	
		Min, Max	146, 2066		241, 1440		270, 1058	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1.1 Descriptive Statistics of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set****Product Use Time Period: Period 1**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Day 5	n	73	69	34	34	22	21
		Missing, n(%)	2 (2.7)	6 (8.0)	1 (2.9)	1 (2.9)	2 (8.3)	3 (12.5)
		Geometric Mean (CV%)	522.4 (44.20)		638.8 (38.60)		499.3 (40.12)	
		95% CI of Geometric Mean	473.3, 576.5		560.9, 727.6		420.6, 592.6	
		Median	545.1	-10.4	640.8	0.9	510.6	-8.3
		Q25, Q75	366.8, 683.3	-23.1, -0.1	495.1, 835.4	-12.0, 20.4	409.9, 575.3	-18.4, 2.5
		Min, Max	223, 1542	-67, 166	325, 1349	-37, 203	200, 1027	-58, 33

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1.1 Descriptive Statistics of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Baseline	n	39		33		12	
		Missing, n(%)	1 (2.5)		1 (2.9)		1 (7.7)	
		Geometric Mean (CV%)	610.5 (51.71)		594.1 (40.57)		563.5 (46.62)	
		95% CI of Geometric Mean	521.3, 714.9		517.3, 682.3		425.0, 746.9	
		Median	647.4		594.7		584.0	
		Q25, Q75	461.0, 797.4		434.8, 762.6		387.2, 829.0	
		Min, Max	146, 2066		330, 1440		270, 1056	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1.1 Descriptive Statistics of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Day 30	n	40	39	33	33	13	12
		Missing, n(%)	0	1 (2.5)	1 (2.9)	1 (2.9)	0	1 (7.7)
		Geometric Mean (CV%)	409.6 (55.38)		453.2 (59.10)		407.3 (46.61)	
		95% CI of Geometric Mean	347.1, 483.3		373.2, 550.3		311.5, 532.5	
		Median	452.2	-25.2	497.3	-19.4	390.6	-27.1
		Q25, Q75	329.8, 567.5	-47.4, -11.1	393.0, 632.2	-34.9, 3.2	348.8, 560.6	-41.2, -13.8
		Min, Max	78, 1058	-81, 101	93, 1080	-85, 62	180, 851	-65, 7

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.



Table 15.2.4.32.1.1 Descriptive Statistics of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set

Product Use Time Period: Period 3

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Baseline	n	37		34		11	
		Missing, n(%)	2 (5.1)		1 (2.9)		1 (8.3)	
		Geometric Mean (CV%)	632.5 (45.07)		578.5 (43.28)		552.1 (43.56)	
		95% CI of Geometric Mean	548.0, 730.0		500.6, 668.6		417.2, 730.5	
		Median	658.9		584.7		553.8	
		Q25, Q75	467.2, 794.7		400.0, 762.6		375.0, 680.5	
		Min, Max	277, 2066		241, 1440		270, 1056	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1.1 Descriptive Statistics of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Day 60	n	39	37	33	33	11	11
		Missing, n(%)	0	2 (5.1)	2 (5.7)	2 (5.7)	1 (8.3)	1 (8.3)
		Geometric Mean (CV%)	446.3 (62.33)		417.8 (66.66)		297.4 (117.39)	
		95% CI of Geometric Mean	370.6, 537.4		336.9, 518.0		159.1, 555.8	
		Median	508.8	-23.0	475.7	-15.3	489.5	-20.5
		Q25, Q75	370.3, 620.3	-44.9, 3.0	289.7, 614.1	-39.9, -1.8	109.3, 585.9	-74.8, -13.9
		Min, Max	72, 1230	-89, 159	85, 1414	-85, 62	70, 844	-81, 54

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1.1 Descriptive Statistics of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Baseline	n	45		32		9	
		Missing, n(%)	2 (4.3)		0		0	
		Geometric Mean (CV%)	611.9 (48.66)		575.6 (44.39)		518.1 (42.83)	
		95% CI of Geometric Mean	532.7, 702.9		494.0, 670.8		377.9, 710.2	
		Median	647.4		584.7		553.8	
		Q25, Q75	467.2, 796.0		399.1, 770.4		375.0, 643.9	
		Min, Max	146, 2066		241, 1440		270, 1056	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.1.1 Descriptive Statistics of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Day 90	n	47	45	31	31	9	9
		Missing, n(%)	0	2 (4.3)	1 (3.1)	1 (3.1)	0	0
		Geometric Mean (CV%)	421.4 (66.64)		431.1 (66.12)		372.1 (72.81)	
		95% CI of Geometric Mean	352.7, 503.5		345.6, 537.7		225.4, 614.4	
		Median	471.8	-22.0	529.4	-14.1	501.3	-22.1
		Q25, Q75	350.7, 601.2	-36.3, -6.7	333.9, 600.9	-45.9, 5.4	281.4, 552.4	-31.7, -12.0
		Min, Max	74, 1243	-88, 70	64, 1250	-83, 142	121, 721	-75, 54

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Prostaglandin F2 Alpha (pg/mg creat)	Baseline	n	73		40		36	
		Missing, n(%)	7 (8.8)		1 (2.4)		3 (7.7)	
		Geometric Mean (CV%)	247.7 (36.29)		268.1 (50.28)		274.2 (47.51)	
		95% CI of Geometric Mean	228.1, 268.9		230.3, 312.1		235.3, 319.5	
		Median	249.3		274.5		266.3	
		Q25, Q75	196.2, 319.1		183.2, 381.0		199.6, 376.7	
		Min, Max	120, 513		96, 851		117, 694	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Prostaglandin F2 Alpha (pg/mg creat)	Day 5	n	77	73	40	40	37	36
		Missing, n(%)	3 (3.8)	7 (8.8)	1 (2.4)	1 (2.4)	2 (5.1)	3 (7.7)
		Geometric Mean (CV%)	216.0 (36.58)		271.9 (44.98)		251.6 (52.60)	
		95% CI of Geometric Mean	199.3, 234.2		237.0, 312.0		213.3, 296.7	
		Median	211.8	-10.9	267.7	-1.2	253.2	-5.9
		Q25, Q75	173.3, 260.0	-22.6, 0.4	192.1, 389.4	-8.1, 9.9	168.9, 367.6	-18.9, 0.7
		Min, Max	94, 500	-55, 42	111, 714	-37, 116	101, 731	-50, 129

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Prostaglandin F2 Alpha (pg/mg creat)	Day 30	n	77	73	40	40	37	36
		Missing, n(%)	3 (3.8)	7 (8.8)	1 (2.4)	1 (2.4)	2 (5.1)	3 (7.7)
		Geometric Mean (CV%)	278.1 (45.26)		324.0 (56.66)		300.4 (53.65)	
		95% CI of Geometric Mean	252.1, 306.8		273.7, 383.6		254.0, 355.3	
		Median	270.1	9.0	310.2	19.0	305.9	0.0
		Q25, Q75	204.1, 346.6	-3.4, 27.2	212.4, 477.5	1.2, 39.6	224.8, 432.3	-15.4, 32.5
		Min, Max	109, 1412	-56, 124	112, 1140	-46, 204	101, 865	-48, 282

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Prostaglandin F2 Alpha (pg/mg creat)	Day 60	n	77	73	40	40	37	36
		Missing, n(%)	3 (3.8)	7 (8.8)	1 (2.4)	1 (2.4)	2 (5.1)	3 (7.7)
		Geometric Mean (CV%)	271.8 (52.62)		310.2 (55.88)		290.9 (46.55)	
		95% CI of Geometric Mean	242.9, 304.1		262.5, 366.5		251.0, 337.3	
		Median	262.6	4.0	298.0	5.6	300.8	0.0
		Q25, Q75	188.7, 357.5	-9.3, 31.7	208.6, 440.7	-5.5, 34.7	235.3, 399.4	-10.2, 31.5
		Min, Max	98, 1697	-54, 281	130, 1063	-32, 128	95, 659	-37, 128

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Prostaglandin F2 Alpha (pg/mg creat)	Day 90	n	77	73	40	40	37	36
		Missing, n(%)	3 (3.8)	7 (8.8)	1 (2.4)	1 (2.4)	2 (5.1)	3 (7.7)
		Geometric Mean (CV%)	267.6 (51.52)		312.9 (49.40)		286.0 (39.96)	
		95% CI of Geometric Mean	239.7, 298.9		269.4, 363.3		251.6, 325.3	
		Median	256.4	6.7	338.6	13.0	305.9	0.0
		Q25, Q75	193.0, 357.5	-14.0, 25.7	212.9, 401.7	0.2, 33.5	221.9, 372.9	-11.1, 20.7
		Min, Max	92, 1236	-47, 112	151, 1158	-31, 119	127, 538	-44, 149

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Baseline	n	73		40		36	
		Missing, n(%)	7 (8.8)		1 (2.4)		3 (7.7)	
		Geometric Mean (CV%)	584.5 (52.98)		595.8 (44.15)		547.9 (44.50)	
		95% CI of Geometric Mean	520.4, 656.5		520.6, 682.0		474.5, 632.7	
		Median	639.3		584.7		539.2	
		Q25, Q75	400.5, 797.1		424.4, 776.0		455.8, 662.2	
		Min, Max	146, 2066		241, 1440		146, 1307	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Day 5	n	77	73	40	40	37	36
		Missing, n(%)	3 (3.8)	7 (8.8)	1 (2.4)	1 (2.4)	2 (5.1)	3 (7.7)
		Geometric Mean (CV%)	528.2 (44.21)		644.1 (38.54)		505.0 (36.57)	
		95% CI of Geometric Mean	479.9, 581.4		571.8, 725.6		448.7, 568.4	
		Median	545.1	-10.4	640.8	1.5	514.3	-2.4
		Q25, Q75	375.9, 683.3	-23.3, -0.1	497.9, 846.7	-9.6, 18.2	409.9, 580.4	-17.6, 2.3
		Min, Max	223, 1542	-67, 166	325, 1349	-37, 203	200, 1027	-58, 152

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Day 30	n	77	73	40	40	37	36
		Missing, n(%)	3 (3.8)	7 (8.8)	1 (2.4)	1 (2.4)	2 (5.1)	3 (7.7)
		Geometric Mean (CV%)	441.4 (59.03)		486.8 (59.01)		452.8 (48.08)	
		95% CI of Geometric Mean	389.8, 499.7		408.7, 579.9		388.9, 527.2	
		Median	476.5	-19.4	508.9	-15.6	440.3	-14.8
		Q25, Q75	333.6, 613.1	-38.9, 8.3	397.8, 695.9	-34.1, 4.3	372.3, 604.1	-32.1, 0.0
		Min, Max	78, 1143	-81, 151	93, 1349	-85, 198	104, 1040	-65, 79

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Day 60	n	77	73	40	40	37	36
		Missing, n(%)	3 (3.8)	7 (8.8)	1 (2.4)	1 (2.4)	2 (5.1)	3 (7.7)
		Geometric Mean (CV%)	437.0 (70.73)		435.5 (73.59)		382.8 (84.26)	
		95% CI of Geometric Mean	378.1, 505.0		352.9, 537.6		299.8, 488.8	
		Median	506.3	-22.3	494.2	-15.7	500.9	-19.5
		Q25, Q75	326.3, 640.5	-43.8, -4.1	309.6, 649.9	-39.6, -1.4	341.3, 580.4	-44.1, 0.0
		Min, Max	71, 2821	-89, 159	84, 1414	-85, 62	70, 1113	-83, 81

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2 (pg/mg creat) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Day 90	n	77	73	40	40	37	36
		Missing, n(%)	3 (3.8)	7 (8.8)	1 (2.4)	1 (2.4)	2 (5.1)	3 (7.7)
		Geometric Mean (CV%)	418.3 (76.78)		447.2 (69.99)		442.1 (64.39)	
		95% CI of Geometric Mean	358.4, 488.3		365.4, 547.3		363.2, 538.0	
		Median	471.8	-24.7	531.1	-14.1	481.5	-9.0
		Q25, Q75	322.6, 602.2	-35.0, -7.6	350.7, 626.0	-42.1, 4.6	417.2, 580.4	-29.4, 1.0
		Min, Max	40, 3671	-89, 173	64, 1349	-85, 142	91, 974	-77, 54

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.2.1 Descriptive Statistics of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Baseline	n	73		40		35	
		Missing, n(%)	7 (8.8)		1 (2.4)		4 (10.3)	
		Geometric Mean (CV%)	584.5 (52.98)		595.8 (44.15)		569.1 (37.70)	
		95% CI of Geometric Mean	520.4, 656.5		520.6, 682.0		502.0, 645.0	
		Median	639.3		584.7		539.9	
		Q25, Q75	400.5, 797.1		424.4, 776.0		458.7, 680.5	
		Min, Max	146, 2066		241, 1440		270, 1307	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.2.1 Descriptive Statistics of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Day 5	n	77	73	40	40	36	35
		Missing, n(%)	3 (3.8)	7 (8.8)	1 (2.4)	1 (2.4)	3 (7.7)	4 (10.3)
		Geometric Mean (CV%)	528.2 (44.21)		644.1 (38.54)		509.5 (36.67)	
		95% CI of Geometric Mean	479.9, 581.4		571.8, 725.6		451.7, 574.6	
		Median	545.1	-10.4	640.8	1.5	521.8	-3.3
		Q25, Q75	375.9, 683.3	-23.3, -0.1	497.9, 846.7	-9.6, 18.2	413.0, 594.9	-18.4, 2.1
		Min, Max	223, 1542	-67, 166	325, 1349	-37, 203	200, 1027	-58, 33

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.2.1 Descriptive Statistics of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Day 30	n	77	73	40	40	36	35
		Missing, n(%)	3 (3.8)	7 (8.8)	1 (2.4)	1 (2.4)	3 (7.7)	4 (10.3)
		Geometric Mean (CV%)	441.4 (59.03)		486.8 (59.01)		471.7 (40.32)	
		95% CI of Geometric Mean	389.8, 499.7		408.7, 579.9		413.6, 537.9	
		Median	476.5	-19.4	508.9	-15.6	455.0	-14.7
		Q25, Q75	333.6, 613.1	-38.9, 8.3	397.8, 695.9	-34.1, 4.3	375.6, 612.0	-33.3, 0.0
		Min, Max	78, 1143	-81, 151	93, 1349	-85, 198	180, 1040	-65, 79

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.2.1 Descriptive Statistics of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Day 60	n	77	73	39	39	36	35
		Missing, n(%)	3 (3.8)	7 (8.8)	2 (4.9)	2 (4.9)	3 (7.7)	4 (10.3)
		Geometric Mean (CV%)	437.0 (70.73)		429.8 (74.04)		398.3 (79.74)	
		95% CI of Geometric Mean	378.1, 505.0		346.9, 532.6		314.1, 505.0	
		Median	506.3	-22.3	488.4	-15.3	506.3	-18.5
		Q25, Q75	326.3, 640.5	-43.8, -4.1	289.7, 641.5	-39.9, -1.0	347.8, 583.1	-44.8, 0.0
		Min, Max	71, 2821	-89, 159	84, 1414	-85, 62	70, 1113	-83, 81

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.32.2.1 Descriptive Statistics of 11-DTX-B2 (pg/mg creat) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
11-Dehydro-Thr omboxane B2 (pg/mg creat)	Day 90	n	77	73	39	39	36	35
		Missing, n(%)	3 (3.8)	7 (8.8)	2 (4.9)	2 (4.9)	3 (7.7)	4 (10.3)
		Geometric Mean (CV%)	418.3 (76.78)		441.6 (70.42)		455.7 (61.61)	
		95% CI of Geometric Mean	358.4, 488.3		359.5, 542.6		376.1, 552.1	
		Median	471.8	-24.7	529.4	-14.0	491.2	-12.0
		Q25, Q75	322.6, 602.2	-35.0, -7.6	333.9, 617.3	-45.9, 5.4	425.3, 586.4	-30.4, 0.1
		Min, Max	40, 3671	-89, 173	64, 1349	-85, 142	91, 974	-77, 54

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.1 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - PP Set****Product Use Time Period: Period 1**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Body weight (kg)	Baseline	n	75		35		24	
		Mean (SD)	79.42 (13.858)		76.58 (13.148)		75.18 (11.197)	
		95% CI	76.23, 82.61		72.06, 81.10		70.45, 79.91	
		Median	78.70		75.40		74.10	
		Q25, Q75	68.90, 89.60		65.70, 87.00		69.35, 82.45	
		Min, Max	52.9, 115.3		49.3, 103.2		48.1, 97.1	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.1 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - PP Set****Product Use Time Period: Period 1**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Body weight (kg)	Day 6/Discharge Confinement	n	75	75	34	34	24	24
		Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
		Mean (SD)	78.60 (13.606)	-0.99 (1.530)	76.13 (12.829)	-0.79 (1.215)	74.36 (10.803)	-1.01 (2.180)
		95% CI	75.47, 81.74	-1.35, -0.63	71.65, 80.61	-1.22, -0.36	69.79, 78.92	-1.94, -0.08
		Median	77.10	-0.93	76.00	-0.91	74.60	-1.03
		Q25, Q75	67.60, 88.20	-2.03, 0.00	65.40, 86.50	-1.72, 0.00	68.00, 80.90	-1.81, 0.46
		Min, Max	53.4, 112.9	-6.8, 2.4	49.1, 101.9	-2.7, 1.6	48.3, 95.0	-9.1, 1.8

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.1 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Body weight (kg)	Baseline	n	40		34		13	
		Mean (SD)	78.82 (14.583)		77.02 (13.077)		70.55 (10.279)	
		95% CI	74.15, 83.49		72.45, 81.59		64.33, 76.76	
		Median	79.35		76.15		72.70	
		Q25, Q75	66.70, 90.80		66.10, 87.00		63.30, 77.30	
		Min, Max	52.9, 108.7		49.3, 103.2		48.1, 87.7	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.1 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - PP Set****Product Use Time Period: Period 2**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Body weight (kg)	Day 30	n	39	39	33	33	13	13
		Missing, n(%)	1 (2.5)	1 (2.5)	1 (2.9)	1 (2.9)	0	0
		Mean (SD)	79.94 (15.090)	1.42 (1.739)	77.91 (13.460)	0.70 (1.750)	71.91 (10.057)	2.07 (3.659)
		95% CI	75.05, 84.84	0.85, 1.99	73.13, 82.68	0.08, 1.33	65.83, 77.99	-0.15, 4.28
		Median	80.80	1.38	78.60	0.89	73.60	1.24
		Q25, Q75	67.40, 90.50	0.35, 2.37	66.70, 88.00	-0.17, 1.84	66.30, 78.10	0.14, 2.96
		Min, Max	53.6, 112.7	-3.9, 4.8	51.0, 104.8	-2.7, 4.1	48.4, 90.3	-2.0, 11.1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.1 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Body weight (kg)	Baseline	n	39		35		12	
		Mean (SD)	80.57 (15.677)		76.57 (13.155)		70.78 (11.306)	
		95% CI	75.48, 85.65		72.04, 81.09		63.60, 77.97	
		Median	83.00		75.40		71.70	
		Q25, Q75	67.00, 91.10		65.70, 87.00		62.80, 77.45	
		Min, Max	52.9, 115.3		49.3, 103.2		48.1, 87.7	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.1 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - PP Set****Product Use Time Period: Period 3**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Body weight (kg)	Day 60	n	39	39	33	33	11	11
		Missing, n(%)	0	0	2 (5.7)	2 (5.7)	1 (8.3)	1 (8.3)
		Mean (SD)	81.97 (15.979)	1.79 (2.428)	78.20 (13.272)	1.36 (2.403)	71.73 (11.310)	1.79 (3.723)
		95% CI	76.78, 87.15	1.00, 2.58	73.49, 82.91	0.50, 2.22	64.12, 79.33	-0.71, 4.30
		Median	84.70	1.33	78.50	1.04	69.80	1.16
		Q25, Q75	67.50, 91.70	0.41, 3.66	67.20, 87.70	0.00, 3.43	65.20, 78.30	-1.69, 4.37
		Min, Max	55.2, 117.8	-4.3, 8.7	51.7, 103.2	-2.6, 5.7	50.2, 89.6	-3.1, 9.6

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.1 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Body weight (kg)	Baseline	n	47		32		9	
		Mean (SD)	78.94 (14.966)		77.64 (13.191)		67.97 (11.177)	
		95% CI	74.54, 83.34		72.88, 82.40		59.37, 76.56	
		Median	78.80		77.70		68.40	
		Q25, Q75	67.00, 90.50		66.15, 87.20		62.30, 76.00	
		Min, Max	52.9, 115.3		49.3, 103.2		48.1, 85.8	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.1 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Body weight (kg)	Day 91/Discharge n Ambulatory		47	47	32	32	9	9
		Mean (SD)	79.60 (15.247)	0.89 (3.641)	78.39 (13.709)	0.93 (2.905)	68.94 (10.804)	1.69 (5.036)
		95% CI	75.12, 84.08	-0.19, 1.96	73.45, 83.34	-0.13, 1.98	60.63, 77.25	-2.19, 5.56
		Median	79.20	1.27	79.35	0.92	66.90	1.93
		Q25, Q75	66.90, 90.30	-0.83, 2.70	66.50, 87.00	-0.52, 2.50	63.50, 76.00	0.00, 3.88
		Min, Max	54.9, 118.6	-9.2, 10.9	50.7, 104.3	-4.5, 10.3	49.7, 86.5	-7.3, 10.1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.1 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Waist circumference (cm)	Baseline	n	47		32		9	
		Mean (SD)	95.8 (14.89)		97.2 (20.08)		81.9 (8.53)	
		95% CI	91.4, 100.2		89.9, 104.4		75.3, 88.5	
		Median	94.0		91.5		81.0	
		Q25, Q75	85.0, 104.0		83.5, 103.0		76.0, 85.0	
		Min, Max	73, 149		77, 169		73, 98	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.1 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - PP Set****Product Use Time Period: Period 4**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Waist circumference (cm)	Day 91/Discharge n Ambulatory		47	46	32	31	9	9
		Missing, n(%)	0	1 (2.1)	0	1 (3.1)	0	0
		Mean (SD)	95.7 (15.91)	0.5 (12.73)	98.8 (23.03)	4.5 (29.62)	81.7 (7.78)	-0.1 (5.19)
		95% CI	91.0, 100.4	-3.4, 4.3	90.4, 107.1	-6.5, 15.4	75.6, 87.7	-4.1, 4.0
		Median	93.0	0.0	94.5	0.0	80.0	0.0
		Q25, Q75	85.0, 101.0	-3.2, 2.7	85.5, 103.5	-4.3, 4.9	76.0, 85.0	-2.6, 5.3
		Min, Max	68, 163	-35, 68	69, 181	-45, 112	73, 98	-8, 6

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.2 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Body weight (kg)	Baseline	n	79		41		39	
		Missing, n(%)	1 (1.3)		0		0	
		Mean (SD)	78.92 (13.893)		75.59 (12.710)		76.52 (13.682)	
		95% CI	75.80, 82.03		71.57, 79.60		72.08, 80.96	
		Median	78.60		73.70		74.70	
		Q25, Q75	67.80, 88.20		65.70, 83.60		65.90, 83.10	
		Min, Max	52.9, 115.3		49.3, 103.2		48.1, 121.2	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.2 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Body weight (kg)	Day 6/Discharge Confinement	n	79	79	40	40	35	35
		Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	4 (10.3)	4 (10.3)
		Mean (SD)	78.18 (13.619)	-0.89 (1.640)	75.15 (12.388)	-0.71 (1.201)	75.60 (13.478)	-1.08 (2.091)
		95% CI	75.12, 81.23	-1.26, -0.52	71.18, 79.11	-1.10, -0.32	70.97, 80.23	-1.81, -0.36
		Median	76.70	-0.93	74.55	-0.90	74.40	-1.03
		Q25, Q75	67.10, 88.20	-1.97, 0.11	65.25, 83.95	-1.66, 0.00	65.40, 84.40	-1.93, 0.33
		Min, Max	53.4, 112.9	-6.8, 4.6	49.1, 101.9	-2.7, 1.6	48.3, 114.6	-9.1, 1.8

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.2 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Body weight (kg)	Day 30	n	77	77	39	39	33	33
		Missing, n(%)	3 (3.8)	3 (3.8)	2 (4.9)	2 (4.9)	6 (15.4)	6 (15.4)
		Mean (SD)	79.85 (14.310)	1.04 (2.009)	76.62 (13.156)	0.82 (1.724)	76.62 (13.170)	1.25 (2.972)
		95% CI	76.60, 83.10	0.58, 1.50	72.35, 80.88	0.26, 1.38	71.95, 81.30	0.19, 2.31
		Median	79.10	1.18	75.80	0.89	73.60	0.84
		Q25, Q75	69.00, 90.00	0.12, 2.02	66.10, 87.10	-0.17, 2.18	67.00, 82.10	-0.95, 2.73
		Min, Max	53.6, 117.3	-4.6, 5.4	51.0, 104.8	-2.7, 4.1	48.4, 115.7	-4.5, 11.1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.2 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Body weight (kg)	Day 60	n	74	74	37	37	31	31
		Missing, n(%)	6 (7.5)	6 (7.5)	4 (9.8)	4 (9.8)	8 (20.5)	8 (20.5)
		Mean (SD)	78.97 (14.120)	1.03 (3.011)	77.59 (12.989)	1.39 (2.287)	76.12 (13.063)	1.43 (3.167)
		95% CI	75.69, 82.24	0.32, 1.73	73.25, 81.92	0.62, 2.15	71.32, 80.91	0.27, 2.60
		Median	78.15	0.80	77.60	1.21	72.80	1.24
		Q25, Q75	67.50, 89.40	-0.34, 3.13	67.20, 86.10	0.14, 2.85	66.50, 85.80	-1.17, 3.25
		Min, Max	55.2, 117.8	-9.3, 8.7	51.7, 103.2	-2.6, 5.7	50.2, 118.0	-3.6, 9.6

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.2 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Body weight (kg)	Day 91/Discharge n Ambulatory		79	79	41	40	39	35
		Missing, n(%)	1 (1.3)	1 (1.3)	0	1 (2.4)	0	4 (10.3)
		Mean (SD)	79.15 (13.938)	0.39 (3.847)	76.34 (13.206)	0.98 (2.782)	77.06 (13.037)	1.02 (3.845)
		95% CI	76.03, 82.28	-0.48, 1.26	72.17, 80.51	0.08, 1.87	72.83, 81.29	-0.31, 2.34
		Median	77.90	0.77	75.90	0.92	74.90	1.10
		Q25, Q75	67.30, 89.00	-1.62, 2.58	66.10, 86.50	-0.52, 2.87	66.90, 85.60	-2.52, 3.88
		Min, Max	54.9, 118.6	-11.6, 10.9	50.7, 104.3	-4.5, 10.3	49.7, 117.4	-7.3, 10.1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.2 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Waist circumference (cm)	Baseline	n	79		41		39	
		Missing, n(%)	1 (1.3)		0		0	
		Mean (SD)	95.7 (18.33)		93.8 (20.74)		92.1 (11.57)	
		95% CI	91.5, 99.8		87.2, 100.4		88.3, 95.9	
		Median	94.0		91.0		91.0	
		Q25, Q75	85.0, 102.0		83.0, 100.0		84.0, 101.0	
		Min, Max	28, 167		33, 169		73, 121	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.33.2 Descriptive Statistics of Body weight (kg) and waist circumference (cm) - FAS**

Parameter (units)	Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
			Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Waist circumference (cm)	Day 91/Discharge n Ambulatory		79	74	41	35	39	32
		Missing, n(%)	1 (1.3)	6 (7.5)	0	6 (14.6)	0	7 (17.9)
		Mean (SD)	98.7 (22.24)	6.1 (29.96)	95.2 (23.13)	4.2 (27.84)	94.4 (17.60)	3.7 (23.32)
		95% CI	93.7, 103.7	-0.9, 13.1	87.8, 102.5	-5.5, 13.8	88.6, 100.1	-4.7, 12.2
		Median	95.0	1.0	92.0	1.0	91.0	0.5
		Q25, Q75	86.0, 101.0	-3.2, 3.7	84.0, 101.0	-3.8, 4.9	85.0, 103.0	-1.8, 4.9
		Min, Max	68, 181	-38, 171	33, 181	-45, 112	73, 173	-16, 128

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit - PP Set**

Biomarker	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
MHBMA (pg/mg creat)						
- 4H						
	n	47	32	9		
	Geometric LS Mean (CV%)	121.30	793.12	152.21	15.29 (94.67)	79.69 (94.67)
	95% CI	95.62, 153.87	596.62, 1054.32	88.66, 261.30	10.55, 22.17	44.30, 143.35
3-HPMA (ng/mg creat)						
- 4H						
	n	47	32	9		
	Geometric LS Mean (CV%)	196.36	508.17	126.66	38.64 (55.64)	155.03 (55.64)
	95% CI	168.26, 229.17	422.54, 611.15	89.11, 180.04	30.38, 49.14	105.73, 227.30

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with log-transformed baseline values, sex, average daily mCC consumption, and randomized arm as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit - PP Set**

Biomarker	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-PMA (pg/mg creat) - 4H						
	n	47	32	9		
	Geometric LS Mean (CV%)	173.40	1313.70	121.19	13.20 (111.60)	143.08 (111.60)
	95% CI	132.61, 226.72	954.29, 1808.46	66.01, 222.49	8.70, 20.03	74.06, 276.40
Total NNAL (pg/mg creat) - 4H						
	n	47	32	9		
	Geometric LS Mean (CV%)	43.98	163.85	32.86	26.84 (107.09)	133.86 (107.09)
	95% CI	33.93, 57.00	120.10, 223.53	18.21, 59.29	17.92, 40.20	70.58, 253.87

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with log-transformed baseline values, sex, average daily mCC consumption, and randomized arm as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit - PP Set**

Biomarker	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
Total 1-OHP (pg/mg creat) - 4H						
	n	47	32	9		
	Geometric LS Mean (CV%)	81.86	136.95	74.19	59.78 (40.79)	110.35 (40.79)
	95% CI	72.69, 92.20	119.10, 157.46	56.76, 96.96	49.73, 71.85	82.21, 148.11
NNN (pg/mg creat) - 4H						
	n	47	32	9		
	Geometric LS Mean (CV%)	0.77	4.42	0.19	17.54 (101.69)	412.96 (101.69)
	95% CI	0.60, 1.00	3.27, 5.96	0.10, 0.34	11.89, 25.86	221.82, 768.80

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with log-transformed baseline values, sex, average daily mCC consumption, and randomized arm as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit - PP Set**

Biomarker	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
4-ABP (pg/mg creat) - 4H						
	n	46	32	9		
	Geometric LS Mean (CV%)	3.16	12.76	2.49	24.75 (95.26)	126.88 (95.26)
	95% CI	2.48, 4.03	9.59, 16.99	1.44, 4.29	17.04, 35.95	70.29, 229.01
1-NA (pg/mg creat) - 4H						
	n	47	32	9		
	Geometric LS Mean (CV%)	5.15	66.86	4.10	7.71 (85.60)	125.64 (85.60)
	95% CI	4.13, 6.42	51.36, 87.05	2.48, 6.77	5.47, 10.85	72.95, 216.35

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with log-transformed baseline values, sex, average daily mCC consumption, and randomized arm as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit - PP Set**

Biomarker	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
2-NA (pg/mg creat) - 4H						
	n	47	32	9		
	Geometric LS Mean (CV%)	2.76	17.10	2.99	16.12 (74.96)	92.32 (74.96)
	95% CI	2.26, 3.36	13.48, 21.68	1.90, 4.69	11.84, 21.94	56.58, 150.64
o-tol (pg/mg creat) - 4H						
	n	47	32	9		
	Geometric LS Mean (CV%)	50.17	108.82	51.85	46.10 (65.63)	96.75 (65.63)
	95% CI	41.99, 59.92	87.95, 134.64	34.61, 77.67	34.98, 60.75	62.40, 149.99

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with log-transformed baseline values, sex, average daily mCC consumption, and randomized arm as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit - PP Set**

Biomarker	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CEMA (ng/mg creat) - 4H						
	n	47	32	9		
	Geometric LS Mean (CV%)	9.88	77.09	10.43	12.81 (99.56)	94.65 (99.56)
	95% CI	7.72, 12.63	57.40, 103.52	5.95, 18.28	8.73, 18.79	51.56, 173.76
HEMA (pg/mg creat) - 4H						
	n	47	32	9		
	Geometric LS Mean (CV%)	1093.15	2501.18	1057.69	43.71 (57.30)	103.35 (57.30)
	95% CI	933.75, 1279.77	2069.41, 3023.04	737.20, 1517.52	34.18, 55.87	69.92, 152.77

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with log-transformed baseline values, sex, average daily mCC consumption, and randomized arm as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit - PP Set**

Biomarker	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
B[a]P (fg/mg creat) - 4H						
	n	46	32	9		
	Geometric LS Mean (CV%)	47.45	97.27	40.32	48.78 (76.83)	117.69 (76.83)
	95% CI	38.45, 58.55	76.28, 124.03	25.35, 64.10	35.29, 67.43	70.63, 196.10
HMPMA (ng/mg creat) - 4H						
	n	47	32	9		
	Geometric LS Mean (CV%)	68.89	241.18	82.71	28.56 (80.31)	83.30 (80.31)
	95% CI	55.83, 85.00	187.61, 310.04	51.34, 133.21	20.58, 39.65	49.61, 139.86

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with log-transformed baseline values, sex, average daily mCC consumption, and randomized arm as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit - PP Set**

Biomarker	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
S-BMA (pg/mg creat) - 4H						
	n	47	32	9		
	Geometric LS Mean (CV%)	3464.77	2941.21	3593.26	117.80 (82.55)	96.42 (82.55)
	95% CI	2796.60, 4292.59	2276.45, 3800.09	2203.02, 5860.80	84.39, 164.44	56.85, 163.55
NEQ (mg/g creat) - 4H						
	n	47	31	9		
	Geometric LS Mean (CV%)	6.61	7.30	0.63	90.57 (78.68)	1046.31 (78.68)
	95% CI	5.38, 8.12	5.67, 9.40	0.39, 1.01	65.57, 125.09	629.49, 1739.12

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with log-transformed baseline values, sex, average daily mCC consumption, and randomized arm as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.35 Descriptive Statistics of MHBMA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	BLOQ, n (%)	2 (4.3)		4 (12.5)		0	
	Geometric Mean (CV%)	1222.4 (140.13)		939.8 (184.95)		879.9 (117.93)	
	95% CI of Geometric Mean	900.1, 1660.1		605.5, 1458.6		429.3, 1803.4	
	Median	1518.1		1488.1		642.0	
	Q25, Q75	662.0, 2622.4		313.3, 2426.6		568.4, 1886.2	
	Min, Max	78, 5890		110, 5441		206, 3267	
	Mean (SD)	1823.0 (1460.08)		1607.0 (1378.69)		1286.8 (1185.45)	
	95% CI of Mean	1394.3, 2251.8		1109.8, 2104.1		375.5, 2198.1	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.35 Descriptive Statistics of MHBMA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	BLOQ, n (%)	30 (63.8)		7 (21.9)		5 (55.6)	
	Geometric Mean (CV%)	130.8 (84.49)		726.6 (288.09)		132.6 (72.94)	
	95% CI of Geometric Mean	105.4, 162.3		424.1, 1244.9		80.2, 219.2	
	Median	125.6	-90.5	1396.9	-20.2	142.5	-90.9
	Q25, Q75	78.1, 187.7	-94.5, -80.8	135.8, 2056.6	-44.8, -2.7	76.1, 208.1	-91.8, -74.1
	Min, Max	35, 1897	-98, 0	44, 6873	-89, 626	52, 286	-96, -31
	Mean (SD)	187.8 (275.76)	-82.7 (21.19)	1593.5 (1740.76)	3.6 (121.34)	156.8 (85.80)	-76.2 (24.26)
	95% CI of Mean	106.8, 268.8	-89.0, -76.4	965.8, 2221.2	-40.2, 47.4	90.8, 222.8	-94.8, -57.5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.36 Descriptive Statistics of 3-HPMA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Geometric Mean (CV%)	794.6 (57.54)		689.7 (60.67)		594.0 (57.79)	
	95% CI of Geometric Mean	679.1, 929.7		563.6, 844.0		393.1, 897.4	
	Median	914.7		685.1		621.1	
	Q25, Q75	553.4, 1127.9		456.6, 1073.8		595.1, 753.8	
	Min, Max	164, 2049		251, 1877		162, 1181	
	Mean (SD)	901.2 (435.15)		802.4 (457.53)		656.8 (265.08)	
	95% CI of Mean	773.4, 1029.0		637.4, 967.4		453.0, 860.6	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.36 Descriptive Statistics of 3-HPMA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	Geometric Mean (CV%)	199.7 (48.23)		495.6 (85.42)		113.1 (58.65)	
	95% CI of Geometric Mean	174.6, 228.5		379.4, 647.2		74.4, 171.8	
	Median	191.5	-77.0	533.9	-30.5	106.7	-82.8
	Q25, Q75	155.4, 263.0	-83.8, -65.6	298.4, 816.1	-50.4, 10.4	87.0, 141.2	-87.8, -81.9
	Min, Max	62, 968	-91, 32	68, 1746	-76, 98	45, 286	-92, 10
	Mean (SD)	223.9 (136.11)	-69.6 (23.72)	627.6 (424.41)	-17.4 (43.52)	128.7 (71.66)	-72.7 (32.23)
	95% CI of Mean	183.9, 263.9	-76.6, -62.6	474.6, 780.7	-33.1, -1.6	73.6, 183.8	-97.5, -47.9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.37 Descriptive Statistics of S-PMA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Geometric Mean (CV%)	1655.4 (108.30)		1317.4 (128.02)		1305.0 (130.00)	
	95% CI of Geometric Mean	1278.1, 2144.1		923.6, 1879.2		607.4, 2803.5	
	Median	1748.9		1642.7		886.3	
	Q25, Q75	1064.9, 2919.5		730.1, 2695.3		864.2, 2673.5	
	Min, Max	124, 9361		95, 5477		292, 5673	
	Mean (SD)	2293.8 (1912.54)		1897.1 (1439.22)		1986.7 (1899.29)	
	95% CI of Mean	1732.2, 2855.4		1378.2, 2416.0		526.8, 3446.7	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.37 Descriptive Statistics of S-PMA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	BLOQ, n (%)	5 (10.6)		0		1 (11.1)	
	Geometric Mean (CV%)	189.7 (167.96)		1224.9 (134.24)		115.6 (130.23)	
	95% CI of Geometric Mean	135.0, 266.6		849.4, 1766.2		53.7, 248.7	
	Median	178.2	-86.0	1484.0	-4.9	105.9	-87.7
	Q25, Q75	87.2, 620.7	-95.5, -70.7	677.8, 2713.8	-36.2, 36.0	89.5, 145.2	-96.0, -81.6
	Min, Max	23, 1563	-99, 0	145, 7684	-61, 118	34, 932	-99, -65
	Mean (SD)	337.6 (354.55)	-81.2 (18.33)	1864.8 (1674.51)	1.5 (42.68)	197.7 (281.74)	-85.3 (12.26)
	95% CI of Mean	233.4, 441.7	-86.7, -75.8	1261.0, 2468.5	-13.9, 17.0	-18.9, 414.3	-94.8, -75.9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.38 Descriptive Statistics of NNAL (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	BLOQ, n (%)	1 (2.1)		0		0	
	Geometric Mean (CV%)	196.26 (135.501)		165.98 (89.747)		158.11 (90.905)	
	95% CI of Geometric Mean	145.42, 264.87		125.80, 218.98		87.07, 287.12	
	Median	247.58		147.62		146.50	
	Q25, Q75	149.42, 340.83		108.47, 326.02		77.89, 256.07	
	Min, Max	3.9, 1081.1		30.0, 680.9		67.9, 756.3	
	Mean (SD)	278.34 (212.389)		218.97 (170.244)		215.54 (216.452)	
	95% CI of Mean	215.97, 340.70		157.58, 280.35		49.15, 381.92	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.38 Descriptive Statistics of NNAL (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	BLOQ, n (%)	2 (4.3)		0		2 (22.2)	
	Geometric Mean (CV%)	47.20 (139.687)		155.78 (115.022)		30.81 (255.842)	
	95% CI of Geometric Mean	34.77, 64.06		111.88, 216.91		10.33, 91.90	
	Median	44.33	-75.19	176.82	-2.96	39.50	-59.66
	Q25, Q75	24.21, 112.65	-88.45, -48.38	89.63, 328.82	-20.36, 15.67	22.47, 77.02	-94.43, -40.78
	Min, Max	1.3, 413.2	-96.3, 91.5	20.2, 571.8	-74.3, 174.0	1.9, 206.9	-99.3, -1.1
	Mean (SD)	74.06 (76.805)	-62.94 (37.185)	216.79 (158.242)	2.88 (45.505)	58.70 (63.092)	-58.87 (34.486)
	95% CI of Mean	51.50, 96.61	-73.86, -52.02	159.73, 273.85	-13.53, 19.29	10.20, 107.20	-85.39, -32.36

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.39 Descriptive Statistics of 1-OHP (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Geometric Mean (CV%)	178.45 (53.275)		145.54 (63.317)		113.36 (46.099)	
	95% CI of Geometric Mean	154.08, 206.66		118.05, 179.44		80.89, 158.86	
	Median	186.41		132.86		110.52	
	Q25, Q75	132.54, 261.08		85.31, 215.95		84.33, 161.15	
	Min, Max	41.8, 496.2		61.0, 753.0		66.7, 219.0	
	Mean (SD)	199.73 (93.610)		174.89 (132.129)		123.63 (55.474)	
	95% CI of Mean	172.24, 227.22		127.24, 222.53		80.99, 166.28	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.39 Descriptive Statistics of 1-OHP (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	Geometric Mean (CV%)	88.78 (64.569)		128.34 (63.485)		56.42 (51.448)	
	95% CI of Geometric Mean	74.64, 105.58		104.04, 158.30		38.87, 81.89	
	Median	84.11	-48.90	125.59	-12.54	50.76	-54.10
	Q25, Q75	65.14, 133.33	-61.88, -29.81	78.52, 216.80	-22.80, 4.05	39.73, 81.19	-55.66, -39.44
	Min, Max	24.6, 333.3	-89.4, 0.0	41.8, 308.9	-71.1, 49.4	29.9, 132.7	-68.5, -32.9
	Mean (SD)	105.39 (66.618)	-45.38 (21.492)	149.36 (78.595)	-7.82 (26.442)	62.93 (33.020)	-48.99 (11.601)
	95% CI of Mean	85.82, 124.95	-51.69, -39.06	121.02, 177.70	-17.36, 1.72	37.54, 88.31	-57.91, -40.07

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.40 Descriptive Statistics of Total NNN (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	BLOQ, n (%)	1 (2.1)		0		0	
	Geometric Mean (CV%)	6.763 (159.6689)		6.474 (108.7722)		3.987 (80.9163)	
	95% CI of Geometric Mean	4.859, 9.412		4.707, 8.903		2.310, 6.881	
	Median	8.8121		5.8775		3.7436	
	Q25, Q75	5.4926, 12.6641		3.4235, 11.6823		3.1490, 7.5938	
	Min, Max	0.155, 37.586		0.928, 46.028		0.882, 9.594	
	Mean (SD)	10.2955 (8.25794)		9.4689 (9.43363)		4.8084 (2.81663)	
	95% CI of Mean	7.8708, 12.7202		6.0677, 12.8701		2.6433, 6.9735	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.40 Descriptive Statistics of Total NNN (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	BLOQ, n (%)	8 (17.0)		0		9 (100.0)	
	Geometric Mean (CV%)	0.785 (165.8920)		4.375 (121.7430)		0.133 (59.6145)	
	95% CI of Geometric Mean	0.559, 1.101		3.102, 6.171		0.086, 0.203	
	Median	0.8783	-89.3810	4.1977	-28.5210	0.1055	-97.2087
	Q25, Q75	0.3230, 1.6719	-94.4184, -77.1284	2.2670, 12.4779	-57.4962, -1.6851	0.0980, 0.2028	-97.8857, -92.9558
	Min, Max	0.052, 6.416	-98.786, 54.061	0.923, 20.000	-89.491, 256.951	0.062, 0.285	-98.995, -91.055
	Mean (SD)	1.3650 (1.48472)	-79.5711 (27.68504)	6.5169 (5.52454)	-10.9856 (74.52777)	0.1520 (0.08530)	-95.7969 (2.99278)
	95% CI of Mean	0.9290, 1.8010	-87.6997, -71.4424	4.5250, 8.5087	-37.8558, 15.8845	0.0864, 0.2176	-98.0974, -93.4964

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.41 Descriptive Statistics of 4-ABP (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	46		32		9	
	Missing, n(%)	1 (2.1)		0		0	
	BLOQ, n (%)	1 (2.2)		0		1 (11.1)	
	Geometric Mean (CV%)	16.362 (87.1848)		14.432 (56.1758)		13.209 (104.9988)	
	95% CI of Geometric Mean	13.087, 20.456		11.948, 17.432		6.809, 25.625	
	Median	17.808		13.609		17.108	
	Q25, Q75	11.729, 28.294		9.511, 22.877		11.210, 21.626	
	Min, Max	1.16, 46.26		6.04, 40.45		1.92, 33.76	
	Mean (SD)	20.447 (12.2935)		16.446 (8.5541)		16.787 (9.8838)	
	95% CI of Mean	16.796, 24.099		13.362, 19.531		9.189, 24.385	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.41 Descriptive Statistics of 4-ABP (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	46	32	32	9	9
	Missing, n(%)	0	1 (2.1)	0	0	0	0
	BLOQ, n (%)	19 (40.4)		1 (3.1)		4 (44.4)	
	Geometric Mean (CV%)	3.517 (172.6685)		12.239 (78.3163)		2.223 (57.7890)	
	95% CI of Geometric Mean	2.490, 4.967		9.537, 15.705		1.471, 3.358	
	Median	2.910	-78.587	11.692	-3.892	2.137	-86.791
	Q25, Q75	1.913, 5.596	-91.931, -58.829	8.092, 23.894	-39.297, 12.844	1.954, 2.471	-92.079, -81.912
	Min, Max	0.39, 287.50	-97.72, 66.95	2.09, 36.00	-77.66, 199.80	0.79, 5.23	-95.49, 28.23
	Mean (SD)	11.347 (41.7168)	-68.739 (32.2828)	15.083 (9.3924)	-2.443 (58.5296)	2.510 (1.3184)	-68.825 (42.0338)
	95% CI of Mean	-0.902, 23.596	-78.327, -59.152	11.696, 18.470	-23.545, 18.660	1.497, 3.524	-101.136, -36.515

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.42 Descriptive Statistics of 1-NA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Geometric Mean (CV%)	90.275 (72.2494)		87.398 (47.6088)		72.830 (75.5930)	
	95% CI of Geometric Mean	74.632, 109.197		74.255, 102.867		43.438, 122.108	
	Median	102.817		89.363		89.302	
	Q25, Q75	63.125, 140.135		59.492, 116.952		43.677, 111.479	
	Min, Max	10.23, 250.00		39.80, 211.76		22.26, 170.05	
	Mean (SD)	106.424 (54.3396)		96.368 (43.8326)		86.874 (49.2687)	
	95% CI of Mean	90.469, 122.380		80.564, 112.171		49.003, 124.746	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.42 Descriptive Statistics of 1-NA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	BLOQ, n (%)	20 (42.6)		0		4 (44.4)	
	Geometric Mean (CV%)	5.079 (99.3781)		65.895 (67.7820)		3.787 (75.9661)	
	95% CI of Geometric Mean	3.982, 6.479		52.793, 82.249		2.253, 6.362	
	Median	4.416	-95.239	72.855	-22.634	3.561	-95.596
	Q25, Q75	3.247, 7.041	-97.167, -89.214	41.206, 111.793	-43.426, 2.232	2.535, 4.612	-97.829, -85.791
	Min, Max	1.03, 123.02	-99.31, 0.00	13.43, 167.08	-75.01, 95.89	1.32, 14.91	-99.04, -59.73
	Mean (SD)	8.576 (17.8041)	-89.568 (17.4716)	77.583 (41.3378)	-17.642 (35.9463)	4.753 (4.0534)	-90.058 (12.6596)
	95% CI of Mean	3.348, 13.804	-94.699, -84.438	62.679, 92.487	-30.602, -4.681	1.637, 7.869	-99.790, -80.327

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	12.84 (28.10)		13.14 (28.90)		13.58 (25.05)	
	95% CI of Geometric Mean	11.92, 13.84		11.65, 14.81		11.96, 15.42	
	Median	12.79		12.16		14.00	
	Q25, Q75	10.80, 15.00		10.27, 15.21		12.75, 15.00	
	Min, Max	5.8, 22.1		8.6, 24.8		8.0, 20.4	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	14.18 (25.68)		13.41 (27.46)			
	95% CI of Geometric Mean	13.24, 15.19		11.96, 15.03			
	Mean (SD)		15.10 (29.272)		-0.11 (11.268)		
	95% CI		6.50, 23.70		-4.98, 4.77		
	Median	14.20	13.56	13.08	2.41		
	Q25, Q75	12.20, 16.11	-3.76, 32.44	11.61, 16.05	-7.31, 6.06		
	Min, Max	8.0, 27.6	-48.8, 82.1	8.5, 20.1	-21.9, 24.0		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	14.78 (20.51)		12.88 (28.92)			
	95% CI of Geometric Mean	14.00, 15.61		11.45, 14.48			
	Mean (SD)		17.94 (29.521)		-1.42 (16.885)		
	95% CI		9.16, 26.71		-9.11, 6.27		
	Median	14.65	10.83	13.00	-2.22		
	Q25, Q75	13.11, 16.33	-3.23, 33.06	11.00, 15.50	-10.00, 5.08		
	Min, Max	10.2, 26.1	-32.7, 103.5	7.1, 20.9	-30.3, 38.1		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	13.03 (27.73)		13.04 (29.51)		13.27 (22.29)	
	95% CI of Geometric Mean	11.74, 14.45		11.53, 14.73		11.33, 15.54	
	Median	13.56		12.16		13.92	
	Q25, Q75	10.80, 15.00		10.23, 15.21		12.75, 14.57	
	Min, Max	6.5, 22.1		8.6, 24.8		8.0, 17.7	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	15.18 (27.02)		12.27 (42.19)			
	95% CI of Geometric Mean	13.77, 16.74		10.34, 14.56			
	Mean (SD)		20.61 (38.599)		-0.10 (21.848)		
	95% CI		4.67, 36.54		-11.34, 11.14		
	Median	15.00	26.34	13.50	-3.99		
	Q25, Q75	13.50, 17.00	-10.88, 44.62	9.75, 15.17	-13.00, 3.70		
	Min, Max	9.5, 32.3	-36.7, 127.3	3.0, 27.0	-26.7, 53.3		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	12.95 (31.39)		12.98 (28.94)		14.47 (15.15)	
	95% CI of Geometric Mean	11.50, 14.59		11.54, 14.60		12.88, 16.25	
	Median	13.36		12.13		14.57	
	Q25, Q75	9.89, 16.80		10.25, 15.00		13.56, 16.20	
	Min, Max	6.5, 22.1		8.6, 24.8		10.9, 17.7	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	15.20 (27.25)		13.60 (32.61)			
	95% CI of Geometric Mean	13.57, 17.03		11.54, 16.02			
	Mean (SD)		19.86 (31.471)		-2.99 (15.380)		
	95% CI		5.13, 34.60		-12.76, 6.79		
	Median	15.00	11.82	14.33	-0.88		
	Q25, Q75	14.00, 16.50	0.56, 50.27	11.50, 17.00	-15.47, 5.26		
	Min, Max	7.8, 34.5	-31.6, 75.8	6.5, 23.0	-25.5, 23.6		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	12.99 (29.43)		12.95 (30.12)		13.71 (14.18)	
	95% CI of Geometric Mean	11.74, 14.37		11.40, 14.72		11.82, 15.90	
	Median	13.36		12.10		14.06	
	Q25, Q75	10.33, 16.60		10.20, 15.43		12.75, 15.00	
	Min, Max	6.5, 22.1		8.6, 24.8		10.9, 16.2	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	14.67 (38.34)		11.84 (41.10)			
	95% CI of Geometric Mean	12.96, 16.61		9.73, 14.42			
	Mean (SD)		22.17 (43.546)		-8.25 (18.945)		
	95% CI		4.57, 39.76		-19.70, 3.21		
	Median	15.50	11.06	12.00	-12.79		
	Q25, Q75	13.33, 17.67	0.64, 55.70	7.50, 14.00	-21.25, 0.00		
	Min, Max	5.0, 28.5	-61.1, 130.9	7.0, 24.5	-32.6, 28.2		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	600.85 (36.86)		627.44 (43.24)		643.29 (38.66)	
	95% CI of Geometric Mean	545.59, 661.70		526.81, 747.29		530.98, 779.37	
	Median	595.49		605.00		682.69	
	Q25, Q75	473.80, 688.11		465.05, 747.48		510.56, 776.37	
	Min, Max	308.7, 1914.9		349.4, 2051.6		349.1, 1714.1	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	728.07 (44.60)		609.99 (43.73)			
	95% CI of Geometric Mean	648.89, 816.92		511.22, 727.84			
	Mean (SD)		37.18 (66.300)		-0.88 (14.848)		
	95% CI		17.71, 56.65		-7.31, 5.54		
	Median	756.37	22.11	589.46	-2.26		
	Q25, Q75	568.20, 982.58	-8.94, 72.29	441.49, 789.94	-10.97, 10.46		
	Min, Max	253.5, 1611.8	-78.2, 212.6	336.0, 1690.8	-34.2, 25.3		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	832.89 (35.87)		609.10 (44.33)			
	95% CI of Geometric Mean	759.45, 913.43		511.39, 725.48			
	Mean (SD)		49.03 (71.137)		2.97 (22.874)		
	95% CI		27.90, 70.16		-7.45, 13.39		
	Median	854.26	34.97	574.87	0.81		
	Q25, Q75	678.09, 1076.17	-5.23, 83.89	443.59, 766.37	-12.12, 16.83		
	Min, Max	378.2, 2050.3	-64.1, 267.5	320.5, 1798.3	-34.3, 44.8		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	597.23 (38.11)		634.16 (42.08)		607.43 (30.88)	
	95% CI of Geometric Mean	519.17, 687.01		534.75, 752.05		489.48, 753.79	
	Median	600.01		605.00		655.39	
	Q25, Q75	458.75, 688.11		490.47, 747.48		453.19, 776.37	
	Min, Max	337.0, 1400.5		349.4, 2051.6		374.8, 899.0	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	733.61 (44.44)		639.66 (44.50)			
	95% CI of Geometric Mean	627.82, 857.22		534.56, 765.42			
	Mean (SD)		38.92 (56.763)		1.99 (32.889)		
	95% CI		15.49, 62.36		-14.93, 18.90		
	Median	826.04	36.15	616.90	-9.85		
	Q25, Q75	617.32, 966.90	8.91, 91.00	518.03, 776.24	-20.29, 13.66		
	Min, Max	219.1, 1357.9	-74.6, 117.8	235.2, 1605.1	-33.2, 95.0		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	594.21 (33.24)		621.41 (42.57)		584.42 (27.20)	
	95% CI of Geometric Mean	524.12, 673.67		525.07, 735.43		475.93, 717.65	
	Median	593.54		600.27		572.97	
	Q25, Q75	470.40, 672.28		488.07, 735.63		501.20, 759.64	
	Min, Max	337.0, 1400.5		349.4, 2051.6		374.8, 793.1	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	787.51 (43.03)		644.91 (38.41)			
	95% CI of Geometric Mean	661.71, 937.22		532.94, 780.42			
	Mean (SD)		55.59 (78.376)		-4.21 (27.333)		
	95% CI		18.90, 92.27		-21.58, 13.16		
	Median	860.05	39.44	656.59	-1.49		
	Q25, Q75	575.57, 997.21	-2.95, 90.66	543.56, 802.77	-16.47, 8.01		
	Min, Max	306.7, 1708.8	-32.7, 272.5	290.1, 1438.1	-63.1, 38.3		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	586.53 (32.16)		616.53 (44.38)		584.89 (30.64)	
	95% CI of Geometric Mean	525.72, 654.38		513.24, 740.60		427.15, 800.87	
	Median	596.77		591.86		627.83	
	Q25, Q75	467.00, 677.66		442.02, 735.63		453.19, 759.64	
	Min, Max	337.0, 1400.5		349.4, 2051.6		374.8, 793.1	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	685.37 (58.65)		516.65 (65.84)			
	95% CI of Geometric Mean	571.73, 821.59		383.35, 696.30			
	Mean (SD)		39.28 (67.821)		-3.34 (28.798)		
	95% CI		11.88, 66.67		-20.75, 14.07		
	Median	764.81	41.84	512.15	-7.91		
	Q25, Q75	583.80, 927.62	5.03, 84.65	367.22, 814.99	-24.06, 8.81		
	Min, Max	154.0, 1433.3	-72.8, 204.5	164.6, 1448.4	-48.5, 52.5		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	46.83 (34.35)		47.74 (38.08)		47.58 (38.07)	
	95% CI of Geometric Mean	42.78, 51.25		40.86, 55.77		39.38, 57.49	
	Median	47.17		49.95		45.91	
	Q25, Q75	36.30, 55.96		40.81, 59.56		36.41, 57.52	
	Min, Max	20.5, 110.8		19.7, 95.4		25.4, 110.4	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	51.46 (47.73)		45.46 (37.85)			
	95% CI of Geometric Mean	45.52, 58.16		38.95, 53.06			
	Mean (SD)		16.96 (45.109)		-0.81 (9.859)		
	95% CI		3.72, 30.21		-5.08, 3.46		
	Median	53.38	12.15	46.87	-1.52		
	Q25, Q75	40.67, 68.32	-7.65, 38.08	36.68, 57.83	-5.22, 2.71		
	Min, Max	13.8, 164.3	-78.2, 159.3	22.7, 108.7	-28.8, 19.5		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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Program: t1502044201_ZRHM-REXA-08_US_v1_PMI.sas

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	56.45 (42.01)		47.26 (40.68)			
	95% CI of Geometric Mean	50.72, 62.82		40.21, 55.55			
	Mean (SD)		25.75 (50.931)		4.38 (15.162)		
	95% CI		10.62, 40.88		-2.53, 11.28		
	Median	60.28	12.65	51.55	1.67		
	Q25, Q75	43.42, 70.62	-5.01, 48.39	39.56, 59.26	-0.33, 9.74		
	Min, Max	15.8, 201.9	-55.3, 223.2	18.6, 116.0	-23.3, 50.7		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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Program: t1502044201_ZRHM-REXA-08_US_v1_PMI.sas

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	45.93 (31.82)		48.55 (37.05)		45.93 (38.69)	
	95% CI of Geometric Mean	40.81, 51.70		41.72, 56.49		35.16, 60.00	
	Median	47.59		49.95		54.19	
	Q25, Q75	36.30, 55.96		41.95, 59.56		33.56, 62.27	
	Min, Max	25.6, 87.7		19.7, 95.4		25.4, 70.4	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	48.24 (42.59)		52.15 (28.69)			
	95% CI of Geometric Mean	41.53, 56.04		46.30, 58.73			
	Mean (SD)		14.39 (38.480)		1.66 (21.505)		
	95% CI		-1.50, 30.28		-9.40, 12.73		
	Median	55.07	13.99	50.97	-2.90		
	Q25, Q75	39.23, 64.41	-8.66, 43.84	44.00, 58.99	-7.91, 6.14		
	Min, Max	19.0, 100.0	-61.9, 98.0	34.5, 113.8	-20.6, 74.9		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	46.05 (30.02)		47.77 (37.22)		40.47 (38.15)	
	95% CI of Geometric Mean	41.09, 51.61		41.17, 55.43		30.48, 53.73	
	Median	48.47		49.31		35.52	
	Q25, Q75	35.76, 56.63		41.63, 58.56		30.26, 55.58	
	Min, Max	26.8, 76.0		19.7, 95.4		25.4, 70.4	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	52.00 (52.92)		47.51 (42.71)			
	95% CI of Geometric Mean	42.16, 64.14		38.49, 58.64			
	Mean (SD)		30.97 (54.470)		-1.81 (21.633)		
	95% CI		5.47, 56.47		-15.56, 11.94		
	Median	53.51	19.61	49.69	-0.50		
	Q25, Q75	46.94, 64.52	-5.47, 64.29	38.46, 57.82	-11.15, 8.46		
	Min, Max	12.6, 153.3	-56.4, 161.2	17.3, 102.7	-53.1, 36.2		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	45.28 (29.30)		47.48 (38.92)		42.74 (40.46)	
	95% CI of Geometric Mean	40.96, 50.05		40.36, 55.86		28.40, 64.32	
	Median	45.72		48.98		40.72	
	Q25, Q75	36.30, 54.58		39.99, 60.57		33.56, 62.27	
	Min, Max	25.6, 76.0		19.7, 95.4		25.4, 70.4	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	46.75 (46.44)		43.59 (58.59)			
	95% CI of Geometric Mean	40.34, 54.18		33.27, 57.11			
	Mean (SD)		13.16 (40.283)		5.37 (20.632)		
	95% CI		-3.12, 29.43		-7.10, 17.84		
	Median	48.61	2.78	42.75	5.98		
	Q25, Q75	40.42, 60.39	-14.86, 48.42	34.14, 63.79	-6.64, 15.08		
	Min, Max	7.7, 88.5	-73.2, 88.0	11.8, 101.2	-32.4, 39.8		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	1.55 (32.26)		1.65 (49.94)		1.62 (27.91)	
	95% CI of Geometric Mean	1.42, 1.70		1.34, 2.01		1.40, 1.87	
	Median	1.66		1.75		1.64	
	Q25, Q75	1.16, 1.97		1.26, 2.26		1.54, 1.80	
	Min, Max	0.7, 3.5		0.5, 3.3		1.0, 2.6	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	1.90 (43.87)		1.65 (50.28)			
	95% CI of Geometric Mean	1.69, 2.13		1.34, 2.02			
	Mean (SD)		25.79 (37.459)		4.05 (9.262)		
	95% CI		14.79, 36.80		0.04, 8.06		
	Median	1.92	16.55	1.70	3.00		
	Q25, Q75	1.39, 2.67	0.39, 50.80	1.16, 2.46	-4.10, 13.72		
	Min, Max	0.7, 3.8	-36.3, 163.6	0.4, 3.2	-13.3, 18.8		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	2.10 (47.96)		1.55 (48.40)			
	95% CI of Geometric Mean	1.86, 2.37		1.28, 1.88			
	Mean (SD)		33.70 (38.830)		4.41 (17.494)		
	95% CI		22.16, 45.24		-3.56, 12.37		
	Median	2.27	34.08	1.51	1.63		
	Q25, Q75	1.70, 2.79	5.35, 50.85	1.23, 2.24	-4.66, 9.84		
	Min, Max	0.8, 5.7	-29.0, 182.5	0.4, 3.3	-22.3, 58.0		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	1.55 (26.68)		1.69 (48.12)		1.66 (21.65)	
	95% CI of Geometric Mean	1.40, 1.72		1.39, 2.06		1.42, 1.94	
	Median	1.59		1.86		1.62	
	Q25, Q75	1.23, 1.93		1.36, 2.26		1.54, 1.73	
	Min, Max	0.9, 2.3		0.5, 3.3		1.2, 2.6	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	1.78 (45.00)		1.78 (36.55)			
	95% CI of Geometric Mean	1.52, 2.09		1.53, 2.07			
	Mean (SD)		21.67 (34.816)		-3.90 (11.521)		
	95% CI		7.30, 36.05		-9.83, 2.02		
	Median	1.89	25.02	1.92	-0.74		
	Q25, Q75	1.45, 2.45	-5.45, 44.25	1.42, 2.31	-6.05, 3.36		
	Min, Max	0.7, 3.8	-38.4, 109.1	0.7, 3.0	-29.8, 10.1		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	1.55 (30.06)		1.65 (48.86)		1.40 (20.63)	
	95% CI of Geometric Mean	1.37, 1.74		1.36, 2.01		1.19, 1.64	
	Median	1.64		1.84		1.54	
	Q25, Q75	1.27, 1.93		1.35, 2.22		1.16, 1.62	
	Min, Max	0.7, 2.3		0.5, 3.3		1.0, 1.7	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	1.92 (46.72)		1.61 (59.72)			
	95% CI of Geometric Mean	1.58, 2.32		1.20, 2.14			
	Mean (SD)		30.84 (36.822)		1.15 (12.161)		
	95% CI		13.60, 48.08		-6.58, 8.88		
	Median	2.02	21.64	1.72	2.49		
	Q25, Q75	1.49, 2.58	8.36, 52.78	1.35, 2.44	-8.82, 5.75		
	Min, Max	0.8, 4.0	-25.1, 112.9	0.4, 3.2	-14.7, 27.1		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	1.53 (30.03)		1.60 (49.53)		1.45 (19.67)	
	95% CI of Geometric Mean	1.37, 1.70		1.30, 1.97		1.17, 1.78	
	Median	1.64		1.65		1.54	
	Q25, Q75	1.22, 1.93		1.17, 2.10		1.39, 1.62	
	Min, Max	0.7, 2.3		0.5, 3.3		1.0, 1.7	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	1.93 (43.41)		1.36 (64.57)			
	95% CI of Geometric Mean	1.68, 2.23		1.01, 1.84			
	Mean (SD)		24.70 (35.519)		0.46 (15.700)		
	95% CI		10.35, 39.05		-9.03, 9.96		
	Median	1.98	19.68	1.58	1.06		
	Q25, Q75	1.39, 2.68	-4.60, 54.78	1.21, 2.04	-14.04, 14.77		
	Min, Max	0.9, 4.8	-28.6, 96.7	0.3, 3.1	-26.5, 21.3		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	20.09 (25.48)		21.67 (43.87)		21.97 (33.70)	
	95% CI of Geometric Mean	18.77, 21.51		18.15, 25.88		18.56, 26.01	
	Median	19.94		20.63		21.03	
	Q25, Q75	17.21, 23.23		16.07, 32.40		18.57, 24.42	
	Min, Max	12.8, 42.6		10.1, 42.8		12.6, 39.6	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	26.90 (48.18)		22.15 (46.63)			
	95% CI of Geometric Mean	23.77, 30.44		18.36, 26.72			
	Mean (SD)		46.41 (60.495)		3.94 (15.009)		
	95% CI		28.65, 64.18		-2.55, 10.44		
	Median	29.69	41.42	22.52	4.60		
	Q25, Q75	20.80, 38.94	1.34, 73.89	16.69, 29.73	-6.13, 18.40		
	Min, Max	7.5, 54.1	-59.6, 219.6	8.8, 45.4	-18.5, 28.6		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	30.94 (46.54)		19.97 (46.20)			
	95% CI of Geometric Mean	27.51, 34.80		16.65, 23.95			
	Mean (SD)		56.57 (61.430)		3.02 (25.820)		
	95% CI		38.33, 74.82		-8.74, 14.78		
	Median	31.35	43.20	19.06	-0.44		
	Q25, Q75	21.63, 43.00	12.87, 88.56	15.18, 29.44	-14.16, 18.06		
	Min, Max	12.4, 80.1	-33.8, 249.9	8.7, 45.4	-30.5, 71.9		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	20.31 (25.10)		22.15 (41.21)		21.94 (22.11)	
	95% CI of Geometric Mean	18.48, 22.31		18.74, 26.19		18.76, 25.65	
	Median	19.11		20.63		21.55	
	Q25, Q75	17.93, 22.62		17.10, 32.40		18.79, 24.42	
	Min, Max	12.8, 42.6		10.1, 42.8		15.8, 35.5	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	27.18 (49.95)		21.85 (43.14)			
	95% CI of Geometric Mean	22.85, 32.32		18.35, 26.02			
	Mean (SD)		46.95 (55.526)		-4.31 (22.791)		
	95% CI		24.02, 69.87		-16.03, 7.42		
	Median	32.75	50.55	21.81	-3.93		
	Q25, Q75	21.40, 36.36	25.71, 76.26	17.73, 29.53	-19.11, 6.74		
	Min, Max	8.1, 60.2	-56.5, 162.9	6.7, 40.1	-36.5, 57.2		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	20.16 (25.60)		21.55 (42.97)		20.23 (16.17)	
	95% CI of Geometric Mean	18.28, 22.23		18.18, 25.55		17.88, 22.90	
	Median	19.21		20.62		20.48	
	Q25, Q75	17.57, 22.76		16.34, 32.30		18.59, 22.77	
	Min, Max	12.8, 42.6		10.1, 42.8		14.9, 24.9	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	29.12 (47.85)		21.83 (47.36)			
	95% CI of Geometric Mean	24.03, 35.27		17.32, 27.51			
	Mean (SD)		56.83 (62.882)		-1.26 (24.692)		
	95% CI		27.40, 86.27		-16.96, 14.43		
	Median	29.83	46.32	22.92	-0.01		
	Q25, Q75	22.97, 37.44	28.04, 74.45	16.62, 30.77	-26.40, 13.16		
	Min, Max	11.8, 71.5	-37.0, 212.2	8.6, 42.4	-30.4, 50.4		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	19.99 (24.85)		20.83 (43.02)		19.85 (18.12)	
	95% CI of Geometric Mean	18.35, 21.77		17.43, 24.90		16.43, 23.97	
	Median	19.21		20.53		19.73	
	Q25, Q75	17.21, 22.64		15.81, 32.30		18.59, 22.77	
	Min, Max	12.8, 42.6		10.1, 42.8		14.9, 24.9	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	28.42 (60.56)		16.18 (58.39)			
	95% CI of Geometric Mean	23.59, 34.25		12.35, 21.18			
	Mean (SD)		55.69 (71.870)		-7.55 (26.206)		
	95% CI		26.65, 84.72		-23.39, 8.29		
	Median	32.31	55.35	16.44	-5.78		
	Q25, Q75	19.80, 41.91	18.95, 85.58	11.90, 19.92	-24.72, 10.29		
	Min, Max	6.3, 72.9	-72.1, 242.3	4.4, 43.9	-42.9, 47.7		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	31.68 (29.95)		29.85 (34.26)		30.92 (28.91)	
	95% CI of Geometric Mean	29.26, 34.30		25.93, 34.36		26.72, 35.77	
	Median	31.45		28.51		29.26	
	Q25, Q75	25.88, 38.62		24.44, 36.67		25.37, 39.22	
	Min, Max	17.3, 81.3		15.2, 63.1		17.7, 50.3	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	28.03 (31.66)		28.48 (35.09)			
	95% CI of Geometric Mean	25.78, 30.48		24.66, 32.89			
	Mean (SD)		-7.32 (27.180)		-3.66 (7.816)		
	95% CI		-15.30, 0.67		-7.05, -0.28		
	Median	27.54	-6.00	26.90	-3.85		
	Q25, Q75	22.97, 34.96	-23.82, 6.25	21.52, 37.29	-11.20, 1.05		
	Min, Max	11.6, 51.6	-65.3, 77.0	15.2, 56.2	-15.3, 14.7		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	27.91 (30.69)		31.49 (30.05)			
	95% CI of Geometric Mean	25.77, 30.23		27.89, 35.56			
	Mean (SD)		-5.82 (25.333)		1.65 (10.361)		
	95% CI		-13.35, 1.71		-3.07, 6.38		
	Median	29.52	-9.68	28.45	0.98		
	Q25, Q75	23.33, 34.02	-20.11, 12.54	26.03, 40.32	-4.25, 6.02		
	Min, Max	12.7, 51.6	-56.2, 64.1	20.2, 59.6	-18.6, 26.0		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	31.01 (30.20)		29.38 (34.19)		28.76 (27.65)	
	95% CI of Geometric Mean	27.71, 34.70		25.53, 33.82		23.68, 34.92	
	Median	31.03		27.92		27.38	
	Q25, Q75	24.40, 38.53		24.44, 35.45		24.83, 35.01	
	Min, Max	17.3, 54.4		15.2, 63.1		17.7, 43.7	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	27.97 (30.96)		30.19 (31.19)			
	95% CI of Geometric Mean	25.02, 31.25		26.54, 34.34			
	Mean (SD)		-4.88 (30.389)		6.51 (21.360)		
	95% CI		-17.43, 7.67		-4.48, 17.50		
	Median	28.14	-6.20	27.44	-0.54		
	Q25, Q75	21.85, 35.67	-23.73, 13.89	24.78, 38.80	-5.92, 15.38		
	Min, Max	16.6, 45.5	-55.4, 71.3	17.5, 53.9	-14.6, 74.2		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	31.93 (23.38)		29.63 (33.72)		30.30 (34.44)	
	95% CI of Geometric Mean	29.19, 34.92		25.87, 33.93		23.42, 39.20	
	Median	32.26		28.47		28.75	
	Q25, Q75	27.56, 38.57		24.74, 36.22		24.83, 39.22	
	Min, Max	17.3, 46.6		15.2, 63.1		17.7, 50.3	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	28.26 (39.28)		30.79 (24.24)			
	95% CI of Geometric Mean	24.08, 33.16		27.23, 34.82			
	Mean (SD)		2.15 (45.773)		-1.61 (21.383)		
	95% CI		-19.27, 23.58		-15.20, 11.98		
	Median	27.12	-4.99	30.09	-0.45		
	Q25, Q75	22.50, 37.68	-22.80, 14.92	27.33, 35.73	-9.28, 6.64		
	Min, Max	12.5, 59.5	-55.1, 108.2	18.3, 46.7	-45.9, 47.4		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	31.58 (26.59)		30.38 (33.81)		31.11 (42.81)	
	95% CI of Geometric Mean	28.82, 34.60		26.35, 35.03		20.23, 47.86	
	Median	31.64		28.56		32.36	
	Q25, Q75	26.24, 38.62		24.91, 37.13		23.36, 43.65	
	Min, Max	17.3, 54.1		15.2, 63.1		17.7, 50.3	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	25.34 (42.14)		32.67 (37.79)			
	95% CI of Geometric Mean	22.14, 29.00		27.23, 39.18			
	Mean (SD)		-9.30 (25.577)		6.28 (14.574)		
	95% CI		-19.64, 1.03		-2.53, 15.09		
	Median	25.76	-2.11	29.82	3.84		
	Q25, Q75	21.62, 31.20	-29.11, 8.71	26.06, 37.23	-0.68, 14.55		
	Min, Max	9.5, 50.2	-65.6, 33.3	19.4, 79.0	-22.1, 33.1		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	46.90 (30.44)		44.40 (35.19)		45.33 (29.48)	
	95% CI of Geometric Mean	43.27, 50.84		38.43, 51.29		39.07, 52.58	
	Median	48.13		41.81		41.85	
	Q25, Q75	37.59, 58.41		35.94, 56.08		37.30, 57.93	
	Min, Max	25.4, 120.6		21.8, 98.5		25.9, 76.9	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	42.11 (33.59)		42.50 (36.50)			
	95% CI of Geometric Mean	38.55, 46.01		36.60, 49.35			
	Mean (SD)		-6.10 (28.134)		-2.70 (8.185)		
	95% CI		-14.36, 2.17		-6.24, 0.85		
	Median	43.52	-6.43	38.61	-5.04		
	Q25, Q75	33.58, 53.07	-23.98, 9.51	34.05, 55.47	-8.45, 1.49		
	Min, Max	15.7, 68.8	-68.0, 69.4	20.7, 85.0	-13.9, 18.2		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	41.98 (30.71)		46.89 (29.96)			
	95% CI of Geometric Mean	38.76, 45.46		41.54, 52.93			
	Mean (SD)		-4.58 (26.911)		2.42 (10.225)		
	95% CI		-12.58, 3.41		-2.24, 7.08		
	Median	43.92	-8.55	44.11	1.25		
	Q25, Q75	33.57, 51.50	-22.40, 17.95	37.93, 57.61	-5.43, 5.96		
	Min, Max	21.3, 73.0	-51.0, 59.1	26.8, 88.8	-11.3, 26.5		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	45.80 (30.31)		43.84 (35.19)		41.62 (31.00)	
	95% CI of Geometric Mean	40.91, 51.27		37.95, 50.65		33.51, 51.70	
	Median	48.44		41.13		40.45	
	Q25, Q75	36.71, 56.82		35.94, 56.08		32.15, 56.34	
	Min, Max	25.4, 79.1		21.8, 98.5		25.9, 64.1	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	42.07 (34.52)		44.67 (33.66)			
	95% CI of Geometric Mean	37.19, 47.58		38.89, 51.30			
	Mean (SD)		-3.51 (32.265)		5.21 (20.122)		
	95% CI		-16.83, 9.81		-5.14, 15.56		
	Median	44.89	-9.88	41.13	-0.46		
	Q25, Q75	32.24, 55.21	-30.47, 19.34	33.89, 60.26	-7.22, 10.78		
	Min, Max	23.2, 72.5	-54.6, 77.2	23.4, 80.5	-18.3, 67.9		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	47.87 (23.54)		44.12 (34.56)		43.15 (38.36)	
	95% CI of Geometric Mean	43.74, 52.38		38.40, 50.69		32.46, 57.37	
	Median	49.26		41.28		39.80	
	Q25, Q75	41.00, 57.69		35.99, 53.71		32.15, 57.93	
	Min, Max	26.0, 65.7		21.8, 98.5		25.9, 76.9	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	41.03 (39.52)		45.75 (27.29)			
	95% CI of Geometric Mean	34.93, 48.20		39.85, 52.51			
	Mean (SD)		-3.55 (36.360)		-1.77 (20.956)		
	95% CI		-20.57, 13.47		-15.09, 11.54		
	Median	40.21	-6.68	50.50	-2.15		
	Q25, Q75	33.13, 58.46	-29.28, 16.74	40.18, 54.38	-10.54, 2.38		
	Min, Max	16.8, 72.5	-53.4, 66.0	24.5, 66.9	-44.8, 46.8		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	47.40 (26.25)		44.92 (35.52)		44.10 (47.90)	
	95% CI of Geometric Mean	43.32, 51.87		38.70, 52.15		27.37, 71.06	
	Median	49.26		42.33		45.04	
	Q25, Q75	38.56, 58.41		36.64, 58.46		30.90, 64.10	
	Min, Max	26.0, 79.1		21.8, 98.5		25.9, 76.9	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	38.48 (45.60)		47.17 (36.12)			
	95% CI of Geometric Mean	33.29, 44.49		39.63, 56.14			
	Mean (SD)		-7.01 (28.546)		4.28 (12.153)		
	95% CI		-18.54, 4.53		-3.07, 11.63		
	Median	38.23	-6.36	42.81	3.09		
	Q25, Q75	33.67, 51.46	-25.92, 14.16	37.08, 55.37	1.61, 11.11		
	Min, Max	13.2, 79.9	-63.5, 39.1	29.5, 109.5	-22.4, 28.2		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	320.87 (27.92)		292.73 (20.87)		337.77 (23.95)	
	95% CI of Geometric Mean	297.96, 345.54		268.29, 319.39		299.16, 381.37	
	Median	351.25		285.84		341.57	
	Q25, Q75	260.24, 393.18		257.26, 344.65		300.60, 383.02	
	Min, Max	140.4, 554.0		195.3, 427.9		214.3, 533.5	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	236.33 (25.62)		286.10 (24.49)			
	95% CI of Geometric Mean	220.76, 253.00		258.38, 316.79			
	Mean (SD)		-23.96 (32.253)		-2.85 (11.536)		
	95% CI		-33.44, -14.49		-7.84, 2.15		
	Median	241.91	-28.82	279.02	-1.10		
	Q25, Q75	203.45, 278.37	-41.96, -21.29	245.54, 341.97	-11.29, 5.61		
	Min, Max	94.7, 360.5	-66.6, 139.4	179.1, 451.9	-32.4, 17.7		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	220.68 (31.20)		299.87 (29.32)			
	95% CI of Geometric Mean	203.53, 239.28		266.35, 337.61			
	Mean (SD)		-26.50 (37.704)		-2.12 (13.778)		
	95% CI		-37.70, -15.29		-8.40, 4.16		
	Median	239.25	-31.08	283.93	-0.06		
	Q25, Q75	194.99, 272.82	-45.05, -15.99	249.77, 367.17	-11.01, 4.94		
	Min, Max	92.4, 384.3	-69.4, 173.7	143.5, 510.9	-28.4, 21.7		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	321.88 (31.94)		293.16 (20.79)		355.70 (25.17)	
	95% CI of Geometric Mean	285.90, 362.39		268.77, 319.77		297.91, 424.69	
	Median	351.25		285.84		345.09	
	Q25, Q75	260.24, 397.33		259.14, 344.65		293.55, 434.42	
	Min, Max	140.4, 554.0		195.3, 427.9		242.2, 533.5	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	199.41 (38.28)		288.84 (57.04)			
	95% CI of Geometric Mean	174.11, 228.38		230.85, 361.39			
	Mean (SD)		-34.32 (42.653)		2.85 (21.727)		
	95% CI		-51.94, -16.71		-8.33, 14.03		
	Median	222.18	-45.22	304.81	3.38		
	Q25, Q75	140.63, 269.61	-51.27, -28.30	249.82, 394.13	-6.68, 18.36		
	Min, Max	94.6, 352.8	-75.9, 151.3	33.8, 518.5	-41.5, 37.7		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	307.22 (32.46)		291.76 (20.49)		333.62 (30.76)	
	95% CI of Geometric Mean	271.74, 347.33		268.33, 317.23		264.79, 420.34	
	Median	296.14		285.31		340.65	
	Q25, Q75	245.55, 373.38		259.97, 340.57		272.01, 421.67	
	Min, Max	140.4, 554.0		195.3, 427.9		214.3, 533.5	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	208.12 (42.52)		350.33 (32.69)			
	95% CI of Geometric Mean	175.20, 247.21		297.40, 412.68			
	Mean (SD)		-22.38 (48.116)		13.44 (27.979)		
	95% CI		-44.91, 0.14		-4.34, 31.23		
	Median	217.26	-24.87	304.15	8.25		
	Q25, Q75	153.38, 299.18	-52.19, -11.17	275.56, 474.22	1.07, 20.99		
	Min, Max	78.9, 348.3	-79.4, 146.1	235.2, 636.3	-23.9, 86.8		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	317.89 (30.82)		288.17 (20.66)		311.02 (30.70)	
	95% CI of Geometric Mean	286.18, 353.12		263.79, 314.80		226.99, 426.15	
	Median	330.75		275.46		306.33	
	Q25, Q75	248.47, 397.33		254.55, 340.57		242.23, 421.67	
	Min, Max	140.4, 554.0		195.3, 427.9		214.3, 446.2	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	198.44 (56.15)		309.07 (31.30)			
	95% CI of Geometric Mean	166.66, 236.28		265.48, 359.81			
	Mean (SD)		-27.07 (38.123)		6.92 (29.870)		
	95% CI		-42.47, -11.66		-11.13, 24.98		
	Median	200.93	-29.88	295.96	18.50		
	Q25, Q75	160.82, 262.54	-46.21, -13.86	271.24, 372.11	-15.77, 24.11		
	Min, Max	15.8, 332.2	-96.1, 120.7	163.7, 618.8	-40.4, 53.1		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	25.45 (33.90)		22.66 (26.19)		25.71 (32.64)	
	95% CI of Geometric Mean	23.27, 27.82		20.32, 25.27		21.83, 30.29	
	Median	26.04		22.90		23.75	
	Q25, Q75	20.72, 31.91		20.62, 25.94		20.97, 30.70	
	Min, Max	11.5, 49.9		13.4, 42.6		15.3, 56.5	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	16.87 (38.93)		21.82 (25.01)			
	95% CI of Geometric Mean	15.23, 18.67		19.66, 24.22			
	Mean (SD)		-31.76 (27.876)		-1.43 (14.220)		
	95% CI		-39.95, -23.57		-7.58, 4.73		
	Median	16.66	-38.48	21.29	-5.06		
	Q25, Q75	12.96, 23.32	-50.08, -20.56	18.87, 26.17	-8.44, 7.68		
	Min, Max	7.3, 37.0	-67.5, 87.5	12.4, 43.0	-28.7, 40.5		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	15.07 (43.27)		23.78 (36.57)			
	95% CI of Geometric Mean	13.50, 16.83		20.54, 27.53			
	Mean (SD)		-36.02 (33.350)		2.83 (23.889)		
	95% CI		-45.93, -26.11		-8.05, 13.71		
	Median	15.52	-44.71	23.32	5.71		
	Q25, Q75	11.45, 20.78	-53.79, -22.72	19.82, 28.63	-15.43, 14.16		
	Min, Max	5.9, 38.4	-73.9, 137.6	14.2, 52.2	-36.4, 48.3		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	24.99 (37.95)		22.81 (26.40)		27.49 (32.18)	
	95% CI of Geometric Mean	21.73, 28.74		20.44, 25.46		21.95, 34.41	
	Median	25.89		23.20		27.07	
	Q25, Q75	19.66, 29.30		20.62, 26.32		20.97, 31.19	
	Min, Max	11.5, 49.9		13.4, 42.6		19.1, 56.5	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	13.13 (47.72)		23.82 (38.55)			
	95% CI of Geometric Mean	11.12, 15.51		20.35, 27.87			
	Mean (SD)		-42.86 (36.191)		5.99 (27.229)		
	95% CI		-57.80, -27.92		-8.01, 20.00		
	Median	11.69	-51.07	24.06	8.95		
	Q25, Q75	8.44, 18.42	-64.27, -32.30	19.28, 28.85	-18.13, 19.70		
	Min, Max	7.4, 32.3	-76.7, 99.9	11.3, 50.5	-44.0, 47.6		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	24.03 (40.45)		22.80 (25.83)		23.48 (26.05)	
	95% CI of Geometric Mean	20.66, 27.95		20.53, 25.33		19.28, 28.59	
	Median	24.22		23.03		21.47	
	Q25, Q75	18.38, 28.31		20.82, 26.14		20.39, 30.70	
	Min, Max	11.5, 49.9		13.4, 42.6		15.3, 32.0	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	13.87 (53.60)		26.16 (30.44)			
	95% CI of Geometric Mean	11.22, 17.16		22.44, 30.49			
	Mean (SD)		-31.60 (40.374)		19.65 (43.344)		
	95% CI		-50.50, -12.70		-7.89, 47.20		
	Median	13.00	-43.97	27.56	9.30		
	Q25, Q75	9.76, 21.73	-56.69, -12.70	21.91, 29.99	-0.42, 24.32		
	Min, Max	5.7, 35.0	-86.4, 94.1	17.1, 46.2	-23.1, 145.4		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	24.88 (37.98)		22.56 (26.72)		23.22 (30.03)	
	95% CI of Geometric Mean	21.89, 28.29		20.13, 25.28		17.06, 31.61	
	Median	25.96		22.77		23.33	
	Q25, Q75	19.46, 33.39		20.42, 26.51		19.15, 31.19	
	Min, Max	11.5, 49.9		13.4, 42.6		15.3, 32.0	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	13.65 (57.89)		26.35 (52.16)			
	95% CI of Geometric Mean	11.40, 16.33		20.64, 33.63			
	Mean (SD)		-35.74 (36.586)		19.63 (36.493)		
	95% CI		-50.52, -20.96		-2.43, 41.69		
	Median	13.15	-39.75	25.28	12.43		
	Q25, Q75	9.58, 20.94	-60.48, -27.32	19.37, 39.15	-8.66, 53.37		
	Min, Max	3.2, 31.5	-90.7, 85.4	10.4, 69.0	-43.7, 67.7		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	342.09 (26.39)		315.71 (20.96)		360.96 (23.15)	
	95% CI of Geometric Mean	318.91, 366.95		289.25, 344.60		320.95, 405.94	
	Median	371.99		305.02		359.24	
	Q25, Q75	283.21, 412.35		273.92, 368.89		317.97, 419.35	
	Min, Max	153.1, 588.1		211.2, 465.2		229.2, 554.0	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	266.96 (21.95)		309.85 (24.32)			
	95% CI of Geometric Mean	251.75, 283.08		280.02, 342.86			
	Mean (SD)		-19.96 (30.822)		-2.39 (11.052)		
	95% CI		-29.02, -10.91		-7.18, 2.39		
	Median	271.79	-25.66	307.00	-2.18		
	Q25, Q75	241.67, 303.18	-37.10, -9.09	259.16, 373.46	-10.89, 6.67		
	Min, Max	116.6, 384.6	-62.2, 132.1	193.9, 496.7	-30.5, 17.9		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	255.75 (27.05)		322.16 (27.87)			
	95% CI of Geometric Mean	238.34, 274.43		287.77, 360.66			
	Mean (SD)		-21.64 (35.890)		-1.84 (12.939)		
	95% CI		-32.31, -10.98		-7.74, 4.05		
	Median	275.14	-24.95	313.72	0.84		
	Q25, Q75	221.89, 310.95	-43.50, -12.58	279.50, 385.44	-11.52, 4.83		
	Min, Max	119.9, 402.4	-63.0, 162.7	155.8, 523.3	-26.2, 23.2		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	343.32 (30.37)		316.52 (20.79)		378.79 (23.59)	
	95% CI of Geometric Mean	306.65, 384.38		290.19, 345.25		320.71, 447.39	
	Median	371.99		305.02		365.60	
	Q25, Q75	283.21, 415.24		279.99, 368.89		317.97, 450.24	
	Min, Max	153.1, 588.1		211.2, 465.2		262.9, 554.0	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	231.13 (33.01)		313.19 (53.46)			
	95% CI of Geometric Mean	205.41, 260.07		253.43, 387.04			
	Mean (SD)		-29.62 (40.436)		2.20 (20.205)		
	95% CI		-46.31, -12.92		-8.19, 12.59		
	Median	244.61	-39.99	337.77	2.95		
	Q25, Q75	174.28, 303.84	-45.11, -23.78	277.33, 427.65	-8.34, 17.93		
	Min, Max	102.7, 374.3	-73.9, 144.4	40.5, 548.6	-37.4, 36.1		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	328.41 (30.99)		314.57 (20.59)		354.41 (29.48)	
	95% CI of Geometric Mean	292.03, 369.32		289.19, 342.17		283.89, 442.44	
	Median	317.31		302.41		359.24	
	Q25, Q75	265.67, 394.17		275.73, 364.87		290.80, 446.61	
	Min, Max	153.1, 588.1		211.2, 465.2		229.2, 554.0	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	243.42 (34.14)		376.18 (29.63)			
	95% CI of Geometric Mean	211.57, 280.06		324.07, 436.68			
	Mean (SD)		-17.59 (45.471)		12.80 (26.295)		
	95% CI		-38.87, 3.70		-3.92, 29.51		
	Median	258.88	-23.91	334.91	6.67		
	Q25, Q75	189.71, 336.19	-48.02, -5.51	294.42, 497.14	-0.16, 19.96		
	Min, Max	134.4, 371.3	-66.4, 140.6	269.4, 649.1	-21.2, 81.1		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	338.96 (29.30)		310.28 (20.69)		331.15 (29.70)	
	95% CI of Geometric Mean	306.66, 374.66		283.99, 338.99		244.07, 449.30	
	Median	353.60		298.17		325.02	
	Q25, Q75	266.75, 415.24		272.10, 364.87		262.90, 446.61	
	Min, Max	153.1, 588.1		211.2, 465.2		229.2, 469.0	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	231.07 (51.07)		329.70 (27.64)			
	95% CI of Geometric Mean	196.81, 271.31		288.08, 377.33			
	Mean (SD)		-22.04 (37.087)		6.44 (28.055)		
	95% CI		-37.02, -7.06		-10.52, 23.40		
	Median	252.07	-26.53	313.25	16.50		
	Q25, Q75	200.38, 303.74	-44.72, -6.82	290.31, 399.93	-13.62, 21.50		
	Min, Max	22.1, 367.6	-94.9, 115.2	201.2, 623.2	-34.7, 51.7		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	1826.74 (54.28)		1672.20 (58.40)		1702.99 (58.58)	
	95% CI of Geometric Mean	1592.26, 2095.74		1330.30, 2101.96		1288.03, 2251.62	
	Median	1905.08		1466.15		1447.83	
	Q25, Q75	1204.24, 2460.86		1081.08, 2499.84		1260.93, 2673.24	
	Min, Max	680.9, 6270.0		684.8, 4827.9		695.3, 4314.5	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	1859.53 (67.67)		1583.17 (66.71)			
	95% CI of Geometric Mean	1575.14, 2195.26		1225.36, 2045.45			
	Mean (SD)		22.61 (85.162)		-2.64 (16.258)		
	95% CI		-2.40, 47.62		-9.67, 4.40		
	Median	2041.08	-1.60	1574.42	-6.61		
	Q25, Q75	1275.42, 2622.82	-25.47, 50.58	982.46, 2630.66	-10.86, 4.51		
	Min, Max	377.4, 6983.9	-77.8, 341.7	639.5, 5460.4	-33.2, 46.7		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	2080.22 (53.64)		1757.19 (55.87)			
	95% CI of Geometric Mean	1820.41, 2377.11		1417.08, 2178.93			
	Mean (SD)		34.02 (74.584)		4.92 (25.837)		
	95% CI		11.87, 56.18		-6.85, 16.68		
	Median	2178.78	10.74	1724.00	4.89		
	Q25, Q75	1630.04, 2793.83	-15.81, 68.62	1122.28, 2497.30	-17.65, 17.92		
	Min, Max	639.7, 7227.0	-52.8, 277.8	846.0, 5710.4	-34.7, 53.5		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	1762.39 (58.27)		1614.48 (61.66)		1516.52 (61.70)	
	95% CI of Geometric Mean	1434.78, 2164.82		1270.40, 2051.75		1010.20, 2276.60	
	Median	1714.49		1420.71		1741.42	
	Q25, Q75	1088.31, 2524.75		1057.15, 2499.84		834.13, 2316.73	
	Min, Max	680.9, 6151.9		684.8, 4827.9		695.3, 2987.8	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	2109.55 (60.35)		1607.66 (56.97)			
	95% CI of Geometric Mean	1719.57, 2587.97		1285.22, 2010.98			
	Mean (SD)		36.60 (70.954)		6.64 (36.312)		
	95% CI		7.31, 65.89		-12.04, 25.31		
	Median	1918.06	18.81	1619.37	-5.51		
	Q25, Q75	1616.68, 3370.03	-13.49, 81.43	1060.79, 2088.81	-21.76, 15.72		
	Min, Max	477.9, 6070.7	-62.8, 276.7	686.8, 5397.6	-33.4, 77.5		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	1824.24 (46.64)		1617.51 (60.16)		1593.90 (62.24)	
	95% CI of Geometric Mean	1535.96, 2166.63		1285.94, 2034.56		1026.70, 2474.44	
	Median	1876.51		1426.28		1307.44	
	Q25, Q75	1405.74, 2603.22		1068.28, 2486.67		1123.32, 2846.28	
	Min, Max	680.9, 3975.6		684.8, 4827.9		739.2, 3219.3	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	2345.58 (48.16)		1613.49 (47.91)			
	95% CI of Geometric Mean	1934.20, 2844.46		1277.24, 2038.27			
	Mean (SD)		50.82 (93.298)		-0.46 (28.604)		
	95% CI		7.15, 94.49		-18.64, 17.72		
	Median	2250.29	36.14	1742.53	-0.10		
	Q25, Q75	1525.25, 3747.15	-6.77, 65.47	1102.91, 2016.50	-16.12, 22.45		
	Min, Max	1223.4, 4700.1	-62.1, 370.9	803.4, 4297.5	-58.7, 36.1		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	1787.85 (46.60)		1618.96 (63.14)		1772.86 (67.58)	
	95% CI of Geometric Mean	1531.65, 2086.91		1260.23, 2079.79		931.42, 3374.41	
	Median	1790.93		1426.28		2076.86	
	Q25, Q75	1324.16, 2524.75		1046.02, 2513.02		1173.52, 2987.83	
	Min, Max	680.9, 3975.6		684.8, 4827.9		739.2, 3219.3	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	2160.59 (68.61)		1516.80 (74.54)			
	95% CI of Geometric Mean	1756.47, 2657.68		1089.87, 2110.97			
	Mean (SD)		53.91 (113.558)		7.07 (34.238)		
	95% CI		8.04, 99.78		-13.63, 27.76		
	Median	2448.45	26.98	1460.29	6.22		
	Q25, Q75	1358.89, 3489.21	-12.18, 89.11	1081.26, 2083.91	-14.43, 31.33		
	Min, Max	464.3, 5027.3	-57.7, 516.9	502.6, 5618.1	-52.1, 60.3		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	143.15 (55.90)		127.70 (50.90)		126.21 (63.23)	
	95% CI of Geometric Mean	124.32, 164.82		104.27, 156.39		93.66, 170.05	
	Median	144.00		127.37		154.98	
	Q25, Q75	107.88, 208.65		90.29, 205.37		85.62, 191.04	
	Min, Max	41.0, 412.5		50.5, 257.9		46.9, 279.4	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	131.86 (75.69)		117.84 (58.20)			
	95% CI of Geometric Mean	109.92, 158.17		93.80, 148.03			
	Mean (SD)		5.47 (70.334)		-2.82 (12.991)		
	95% CI		-15.19, 26.12		-8.44, 2.80		
	Median	149.40	-9.22	110.84	-6.36		
	Q25, Q75	86.99, 191.79	-27.28, 19.64	74.87, 196.93	-11.97, 2.94		
	Min, Max	19.2, 646.8	-82.2, 350.5	53.1, 351.5	-17.4, 36.3		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	141.61 (60.31)		136.66 (52.89)			
	95% CI of Geometric Mean	122.15, 164.17		111.33, 167.76			
	Mean (SD)		15.71 (64.789)		6.86 (22.763)		
	95% CI		-3.54, 34.95		-3.50, 17.23		
	Median	145.49	0.15	132.35	1.26		
	Q25, Q75	100.01, 214.36	-20.60, 31.93	103.32, 193.44	-6.80, 9.89		
	Min, Max	26.1, 710.7	-62.2, 254.5	49.0, 368.2	-26.4, 67.6		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	136.09 (59.14)		123.87 (52.52)		114.65 (67.48)	
	95% CI of Geometric Mean	110.50, 167.61		100.56, 152.58		73.97, 177.71	
	Median	139.08		121.93		125.94	
	Q25, Q75	102.13, 208.65		82.56, 205.37		73.05, 169.10	
	Min, Max	41.0, 412.5		50.5, 257.9		46.9, 276.2	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	139.16 (63.37)		131.49 (50.06)			
	95% CI of Geometric Mean	112.45, 172.22		107.69, 160.56			
	Mean (SD)		17.95 (69.646)		5.95 (22.588)		
	95% CI		-10.80, 46.71		-5.67, 17.57		
	Median	132.92	-1.49	124.62	3.22		
	Q25, Q75	97.66, 230.25	-20.00, 27.95	91.43, 180.36	-13.47, 18.03		
	Min, Max	44.1, 449.8	-47.0, 281.6	64.8, 382.9	-25.1, 48.4		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	142.13 (53.07)		124.72 (51.42)		110.47 (77.49)	
	95% CI of Geometric Mean	117.16, 172.41		102.12, 152.33		65.20, 187.14	
	Median	147.23		124.36		96.89	
	Q25, Q75	109.42, 216.35		87.76, 197.29		66.53, 217.57	
	Min, Max	41.0, 305.6		50.5, 257.9		46.9, 276.2	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	154.68 (62.10)		118.94 (51.67)			
	95% CI of Geometric Mean	121.53, 196.86		92.62, 152.74			
	Mean (SD)		30.65 (77.931)		2.98 (30.651)		
	95% CI		-5.83, 67.12		-16.50, 22.46		
	Median	144.42	9.27	118.75	3.39		
	Q25, Q75	109.55, 239.48	-14.96, 63.34	84.76, 171.32	-14.70, 11.55		
	Min, Max	34.6, 400.9	-63.6, 285.3	47.7, 307.0	-47.6, 81.4		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	138.73 (51.89)		125.08 (53.99)		129.77 (79.72)	
	95% CI of Geometric Mean	116.99, 164.50		100.50, 155.66		62.15, 270.92	
	Median	141.44		130.38		157.23	
	Q25, Q75	108.66, 208.65		77.35, 213.44		73.05, 224.24	
	Min, Max	41.0, 305.6		50.5, 257.9		50.1, 276.2	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	148.21 (56.74)		128.25 (61.73)			
	95% CI of Geometric Mean	124.27, 176.76		96.68, 170.13			
	Mean (SD)		31.45 (104.830)		15.66 (22.508)		
	95% CI		-10.90, 73.80		2.06, 29.27		
	Median	157.26	5.88	118.76	15.56		
	Q25, Q75	115.60, 207.89	-18.90, 57.99	93.78, 216.74	10.16, 32.34		
	Min, Max	41.5, 379.0	-58.5, 502.0	35.9, 336.6	-34.7, 41.9		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	266.31 (34.57)		232.81 (45.01)		233.99 (36.74)	
	95% CI of Geometric Mean	243.19, 291.64		194.19, 279.11		194.87, 280.95	
	Median	262.76		214.45		219.81	
	Q25, Q75	209.97, 337.26		183.74, 300.63		177.49, 308.34	
	Min, Max	115.3, 585.9		115.3, 638.8		138.0, 412.8	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	221.31 (37.59)		225.89 (48.12)			
	95% CI of Geometric Mean	200.60, 244.17		186.30, 273.89			
	Mean (SD)		-12.79 (28.418)		-1.97 (10.049)		
	95% CI		-21.14, -4.44		-6.32, 2.38		
	Median	211.79	-19.41	226.63	-3.86		
	Q25, Q75	170.40, 284.50	-31.90, 3.96	165.42, 295.16	-9.63, 3.25		
	Min, Max	88.3, 496.8	-66.4, 93.6	107.1, 668.6	-18.3, 22.3		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	219.38 (39.56)		251.74 (40.74)			
	95% CI of Geometric Mean	198.27, 242.74		214.14, 295.94			
	Mean (SD)		-8.25 (25.480)		2.08 (12.617)		
	95% CI		-15.82, -0.67		-3.67, 7.82		
	Median	218.74	-7.95	251.09	1.16		
	Q25, Q75	162.73, 292.92	-24.06, -0.27	209.38, 301.60	-5.10, 8.87		
	Min, Max	70.9, 448.8	-52.3, 72.6	109.3, 695.4	-16.8, 40.0		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	257.90 (38.72)		221.30 (45.02)		219.95 (33.39)	
	95% CI of Geometric Mean	223.72, 297.30		184.58, 265.32		174.31, 277.54	
	Median	233.85		212.25		227.22	
	Q25, Q75	209.97, 313.92		169.40, 286.41		177.49, 279.63	
	Min, Max	115.3, 585.9		115.3, 638.8		138.0, 355.4	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	252.21 (32.97)		222.39 (34.77)			
	95% CI of Geometric Mean	224.18, 283.75		192.82, 256.49			
	Mean (SD)		5.90 (41.402)		6.51 (18.694)		
	95% CI		-11.20, 22.99		-3.11, 16.13		
	Median	241.46	-6.29	209.90	4.06		
	Q25, Q75	193.11, 330.83	-23.76, 22.52	177.62, 273.77	-6.39, 9.08		
	Min, Max	153.5, 477.9	-43.9, 104.4	131.2, 431.6	-19.2, 56.2		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	267.00 (39.80)		226.97 (46.13)		243.69 (36.88)	
	95% CI of Geometric Mean	230.11, 309.81		189.33, 272.09		185.20, 320.65	
	Median	281.90		212.85		262.52	
	Q25, Q75	210.15, 348.47		180.01, 296.36		187.57, 308.34	
	Min, Max	115.3, 585.9		115.3, 638.8		140.9, 412.8	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	266.05 (42.08)		219.69 (31.32)			
	95% CI of Geometric Mean	224.35, 315.51		187.72, 257.10			
	Mean (SD)		9.46 (57.935)		5.27 (16.104)		
	95% CI		-17.66, 36.58		-4.96, 15.51		
	Median	274.00	-1.37	225.46	0.83		
	Q25, Q75	199.78, 374.14	-29.17, 16.83	195.59, 267.75	-6.13, 9.19		
	Min, Max	134.2, 520.1	-50.2, 159.2	120.7, 334.0	-8.5, 37.9		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	265.42 (37.91)		229.60 (48.14)		273.78 (35.14)	
	95% CI of Geometric Mean	233.56, 301.62		188.47, 279.71		191.37, 391.67	
	Median	256.19		216.05		293.98	
	Q25, Q75	210.33, 328.37		158.79, 304.90		187.57, 355.44	
	Min, Max	115.3, 585.9		115.3, 638.8		177.5, 412.8	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	275.48 (38.14)		256.99 (35.00)			
	95% CI of Geometric Mean	243.63, 311.50		217.02, 304.32			
	Mean (SD)		16.70 (62.654)		10.84 (17.748)		
	95% CI		-8.61, 42.01		0.11, 21.57		
	Median	282.02	2.31	257.94	5.06		
	Q25, Q75	214.35, 340.03	-20.85, 23.19	217.04, 289.71	-2.10, 26.33		
	Min, Max	113.4, 534.8	-45.8, 260.0	131.1, 623.8	-16.1, 42.5		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	419.74 (35.86)		369.68 (45.54)		365.54 (38.31)	
	95% CI of Geometric Mean	382.07, 461.12		307.76, 444.05		302.20, 442.14	
	Median	404.69		366.25		358.21	
	Q25, Q75	328.80, 580.35		302.70, 499.54		266.83, 497.72	
	Min, Max	181.6, 836.0		174.2, 850.6		201.1, 685.8	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	356.48 (41.43)		358.95 (49.85)			
	95% CI of Geometric Mean	320.11, 396.97		294.20, 437.96			
	Mean (SD)		-10.75 (29.557)		-1.35 (9.968)		
	95% CI		-19.43, -2.07		-5.66, 2.97		
	Median	380.56	-17.50	349.79	-1.45		
	Q25, Q75	268.14, 484.88	-31.43, 5.56	266.61, 505.01	-10.24, 4.80		
	Min, Max	120.0, 804.1	-70.4, 109.2	153.1, 891.5	-17.6, 24.4		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	356.75 (39.69)		399.78 (40.44)			
	95% CI of Geometric Mean	322.32, 394.86		340.45, 469.44			
	Mean (SD)		-5.63 (28.094)		2.78 (12.318)		
	95% CI		-13.98, 2.72		-2.84, 8.39		
	Median	366.97	-6.56	393.25	0.82		
	Q25, Q75	266.68, 450.34	-24.29, 8.06	338.81, 505.78	-4.04, 7.44		
	Min, Max	131.7, 720.3	-52.0, 101.0	153.1, 913.9	-12.6, 41.3		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	404.84 (39.06)		353.54 (45.59)		337.89 (36.88)	
	95% CI of Geometric Mean	350.77, 467.23		294.27, 424.74		261.72, 436.23	
	Median	400.50		356.39		359.22	
	Q25, Q75	316.84, 517.77		265.50, 449.49		256.25, 442.96	
	Min, Max	181.6, 836.0		174.2, 850.6		201.1, 567.0	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	411.85 (36.86)		351.68 (39.35)			
	95% CI of Geometric Mean	361.31, 469.46		299.62, 412.79			
	Mean (SD)		9.03 (41.934)		5.26 (17.746)		
	95% CI		-8.29, 26.34		-3.87, 14.39		
	Median	394.63	-4.15	317.99	6.39		
	Q25, Q75	298.02, 560.81	-17.64, 24.44	279.42, 492.62	-6.82, 10.18		
	Min, Max	237.3, 773.0	-43.2, 116.9	185.4, 696.4	-19.6, 47.7		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	426.62 (39.82)		361.47 (46.17)		365.57 (41.70)	
	95% CI of Geometric Mean	367.66, 495.05		301.48, 433.38		268.72, 497.33	
	Median	431.81		361.15		360.24	
	Q25, Q75	340.25, 596.75		291.26, 477.89		266.83, 497.72	
	Min, Max	181.6, 836.0		174.2, 850.6		213.6, 685.8	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	427.95 (45.32)		349.87 (36.85)			
	95% CI of Geometric Mean	356.56, 513.63		291.23, 420.32			
	Mean (SD)		10.60 (56.991)		4.54 (16.175)		
	95% CI		-16.08, 37.28		-5.74, 14.82		
	Median	468.32	-7.09	375.62	-2.89		
	Q25, Q75	304.86, 641.73	-28.04, 23.13	304.12, 470.55	-5.57, 14.10		
	Min, Max	210.6, 822.7	-53.0, 167.5	170.7, 521.9	-10.5, 38.0		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	423.67 (37.63)		363.75 (48.35)		410.25 (42.49)	
	95% CI of Geometric Mean	373.14, 481.03		298.35, 443.49		267.55, 629.06	
	Median	401.81		371.35		428.98	
	Q25, Q75	347.49, 592.87		239.74, 521.19		266.83, 567.03	
	Min, Max	181.6, 836.0		174.2, 850.6		256.2, 685.8	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	457.63 (38.76)		395.19 (35.76)			
	95% CI of Geometric Mean	403.96, 518.43		332.57, 469.59			
	Mean (SD)		23.41 (67.430)		8.90 (17.456)		
	95% CI		-3.83, 50.65		-1.66, 19.45		
	Median	480.95	11.05	377.46	1.72		
	Q25, Q75	362.13, 603.03	-16.17, 30.15	325.46, 463.80	-6.66, 21.69		
	Min, Max	190.4, 804.3	-50.1, 292.4	198.4, 865.3	-8.5, 44.7		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	1.85 (48.82)		2.06 (35.93)		1.84 (48.84)	
	95% CI of Geometric Mean	1.63, 2.10		1.77, 2.39		1.44, 2.34	
	Median	1.69		2.09		2.06	
	Q25, Q75	1.38, 2.29		1.63, 2.57		1.36, 2.56	
	Min, Max	0.7, 10.8		1.0, 4.7		0.8, 3.9	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	2.86 (51.36)		2.02 (39.52)			
	95% CI of Geometric Mean	2.50, 3.26		1.72, 2.38			
	Mean (SD)		87.72 (115.950)		1.37 (16.446)		
	95% CI		53.67, 121.77		-5.75, 8.49		
	Median	2.86	58.53	2.06	4.19		
	Q25, Q75	2.10, 4.09	23.52, 116.62	1.61, 2.66	-10.62, 13.56		
	Min, Max	1.1, 7.0	-86.4, 496.9	0.9, 4.7	-36.8, 32.2		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	3.37 (45.36)		1.95 (45.54)			
	95% CI of Geometric Mean	3.00, 3.78		1.63, 2.34			
	Mean (SD)		111.90 (116.981)		6.69 (30.010)		
	95% CI		77.16, 146.64		-6.97, 20.36		
	Median	3.43	83.13	2.07	1.71		
	Q25, Q75	2.53, 4.64	42.68, 168.23	1.32, 2.57	-14.77, 18.96		
	Min, Max	1.1, 8.7	-89.6, 428.9	0.9, 5.9	-33.5, 93.3		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	1.88 (56.78)		2.08 (35.17)		1.64 (50.69)	
	95% CI of Geometric Mean	1.53, 2.30		1.79, 2.41		1.16, 2.31	
	Median	1.69		2.09		1.83	
	Q25, Q75	1.28, 2.18		1.80, 2.57		1.03, 2.56	
	Min, Max	0.9, 10.8		1.0, 4.7		0.8, 3.0	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	3.23 (55.85)		2.06 (46.92)			
	95% CI of Geometric Mean	2.66, 3.92		1.70, 2.50			
	Mean (SD)		120.59 (119.850)		-0.02 (30.413)		
	95% CI		71.11, 170.06		-15.66, 15.62		
	Median	3.35	95.11	2.22	-7.15		
	Q25, Q75	2.16, 4.37	45.57, 206.10	1.42, 2.44	-22.91, 16.87		
	Min, Max	0.8, 7.1	-87.4, 422.2	1.0, 5.8	-37.2, 77.7		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	1.97 (53.69)		2.05 (35.21)		1.69 (54.13)	
	95% CI of Geometric Mean	1.61, 2.39		1.77, 2.36		1.14, 2.50	
	Median	1.99		2.07		1.60	
	Q25, Q75	1.44, 2.30		1.80, 2.48		1.30, 2.62	
	Min, Max	1.0, 10.8		1.0, 4.7		0.8, 3.2	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	3.26 (56.01)		1.74 (52.45)			
	95% CI of Geometric Mean	2.61, 4.07		1.35, 2.25			
	Mean (SD)		130.59 (179.675)		-14.80 (26.920)		
	95% CI		46.49, 214.68		-31.91, 2.31		
	Median	3.59	88.67	1.83	-16.20		
	Q25, Q75	2.05, 4.95	11.10, 179.65	1.67, 2.11	-28.74, 4.06		
	Min, Max	1.3, 7.5	-86.1, 624.9	0.7, 5.0	-67.3, 28.7		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	1.86 (51.13)		2.06 (36.79)		1.80 (57.22)	
	95% CI of Geometric Mean	1.57, 2.21		1.76, 2.41		1.03, 3.15	
	Median	1.70		2.11		1.87	
	Q25, Q75	1.39, 2.18		1.46, 2.65		1.30, 3.03	
	Min, Max	0.9, 10.8		1.0, 4.7		0.8, 3.2	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	3.00 (60.21)		1.59 (93.35)			
	95% CI of Geometric Mean	2.49, 3.61		1.07, 2.37			
	Mean (SD)		112.35 (159.244)		-1.96 (47.727)		
	95% CI		48.03, 176.68		-30.80, 26.89		
	Median	3.22	67.70	1.57	-6.03		
	Q25, Q75	2.25, 4.38	4.83, 170.70	1.08, 2.94	-32.08, 15.20		
	Min, Max	0.8, 9.1	-85.8, 551.2	0.3, 5.4	-59.4, 128.7		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	6.17 (41.60)		7.11 (35.10)		6.28 (35.35)	
	95% CI of Geometric Mean	5.54, 6.88		6.15, 8.22		5.26, 7.50	
	Median	5.85		7.48		6.95	
	Q25, Q75	4.74, 7.62		5.80, 8.34		4.95, 8.06	
	Min, Max	3.3, 37.2		3.4, 12.8		3.6, 10.2	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	10.54 (54.21)		7.34 (39.55)			
	95% CI of Geometric Mean	9.18, 12.09		6.24, 8.63			
	Mean (SD)		100.25 (101.915)		6.27 (17.697)		
	95% CI		70.32, 130.17		-1.39, 13.92		
	Median	10.48	72.93	7.93	3.31		
	Q25, Q75	6.73, 16.11	30.18, 161.94	5.28, 9.71	-4.69, 16.31		
	Min, Max	3.5, 23.6	-85.3, 451.6	3.4, 12.6	-20.0, 53.1		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	12.55 (52.05)		6.42 (50.94)			
	95% CI of Geometric Mean	11.01, 14.29		5.26, 7.83			
	Mean (SD)		125.21 (108.914)		7.49 (36.810)		
	95% CI		92.86, 157.56		-9.27, 24.25		
	Median	13.27	107.37	7.09	0.35		
	Q25, Q75	8.87, 18.33	53.96, 195.05	4.82, 9.54	-10.38, 20.51		
	Min, Max	4.5, 30.6	-87.6, 491.1	2.4, 14.9	-33.8, 143.9		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	6.38 (48.51)		7.31 (33.12)		5.90 (34.71)	
	95% CI of Geometric Mean	5.35, 7.60		6.37, 8.38		4.63, 7.51	
	Median	5.88		7.60		5.94	
	Q25, Q75	4.93, 7.33		6.32, 8.34		4.78, 7.90	
	Min, Max	3.3, 37.2		3.4, 12.8		3.6, 10.2	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	11.97 (61.49)		7.06 (49.17)			
	95% CI of Geometric Mean	9.72, 14.74		5.79, 8.59			
	Mean (SD)		132.14 (106.775)		-4.70 (28.685)		
	95% CI		88.06, 176.21		-19.45, 10.05		
	Median	12.98	123.33	6.27	-6.96		
	Q25, Q75	7.92, 19.29	65.23, 195.24	5.45, 10.21	-21.08, 3.95		
	Min, Max	3.2, 31.7	-84.5, 343.9	2.6, 16.6	-48.5, 70.4		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	6.65 (47.39)		7.15 (34.42)		5.82 (25.93)	
	95% CI of Geometric Mean	5.58, 7.92		6.22, 8.21		4.78, 7.09	
	Median	6.10		7.51		5.66	
	Q25, Q75	5.05, 7.68		6.15, 8.29		4.95, 6.95	
	Min, Max	3.8, 37.2		3.4, 12.8		3.7, 8.1	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	12.05 (62.90)		5.91 (68.91)			
	95% CI of Geometric Mean	9.44, 15.38		4.28, 8.15			
	Mean (SD)		127.12 (177.322)		-10.70 (25.718)		
	95% CI		44.13, 210.11		-27.04, 5.65		
	Median	11.16	100.32	6.50	-10.62		
	Q25, Q75	7.56, 18.43	44.25, 160.23	4.61, 8.15	-28.16, 11.24		
	Min, Max	3.9, 41.3	-83.3, 802.4	1.5, 14.7	-61.2, 26.2		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	6.32 (46.36)		7.01 (35.15)		6.10 (19.16)	
	95% CI of Geometric Mean	5.41, 7.38		6.04, 8.13		5.00, 7.45	
	Median	5.87		7.44		6.15	
	Q25, Q75	4.93, 7.62		5.45, 8.29		5.23, 6.95	
	Min, Max	3.3, 37.2		3.4, 12.8		4.8, 7.9	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	12.52 (55.02)		5.00 (87.68)			
	95% CI of Geometric Mean	10.54, 14.87		3.43, 7.28			
	Mean (SD)		122.65 (126.761)		-8.45 (39.626)		
	95% CI		71.45, 173.86		-32.40, 15.50		
	Median	13.73	101.06	5.60	-13.84		
	Q25, Q75	9.43, 17.92	57.60, 175.65	3.35, 6.95	-33.98, 13.88		
	Min, Max	3.3, 28.5	-83.9, 439.4	0.7, 20.4	-55.3, 89.8		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Geometric Mean (CV%)	2.38 (41.28)		2.60 (25.59)		2.33 (32.84)	
	95% CI of Geometric Mean	2.13, 2.66		2.34, 2.90		1.97, 2.75	
	Median	2.22		2.63		2.38	
	Q25, Q75	1.92, 2.88		2.22, 2.81		1.94, 2.77	
	Min, Max	1.2, 14.7		1.4, 4.4		1.1, 4.2	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Geometric Mean (CV%)	3.32 (35.36)		2.67 (25.20)			
	95% CI of Geometric Mean	3.02, 3.65		2.40, 2.97			
	Mean (SD)		54.34 (47.449)		1.78 (13.505)		
	95% CI		40.41, 68.28		-4.07, 7.62		
	Median	3.38	51.20	2.71	1.97		
	Q25, Q75	2.65, 3.97	19.71, 82.98	2.25, 3.12	-6.29, 9.91		
	Min, Max	1.6, 6.9	-86.3, 165.7	1.4, 4.7	-27.8, 30.5		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 1**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Geometric Mean (CV%)	3.58 (39.27)		2.50 (35.37)			
	95% CI of Geometric Mean	3.23, 3.96		2.17, 2.89			
	Mean (SD)		66.13 (58.465)		2.86 (25.878)		
	95% CI		48.77, 83.50		-8.93, 14.64		
	Median	3.55	59.35	2.56	-2.34		
	Q25, Q75	2.70, 4.55	24.74, 93.65	2.07, 2.98	-12.56, 16.15		
	Min, Max	1.6, 8.5	-88.9, 201.4	1.2, 4.4	-34.7, 69.5		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Geometric Mean (CV%)	2.48 (51.12)		2.61 (25.64)		2.15 (30.30)	
	95% CI of Geometric Mean	2.06, 2.98		2.34, 2.91		1.73, 2.66	
	Median	2.29		2.63		2.28	
	Q25, Q75	2.14, 2.99		2.22, 2.83		1.88, 2.77	
	Min, Max	1.2, 14.7		1.4, 4.4		1.1, 2.9	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 2**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Geometric Mean (CV%)	4.03 (41.74)		2.37 (36.95)			
	95% CI of Geometric Mean	3.47, 4.67		2.04, 2.77			
	Mean (SD)		89.55 (73.133)		-1.32 (26.533)		
	95% CI		59.36, 119.74		-14.97, 12.33		
	Median	4.42	73.41	2.33	-11.96		
	Q25, Q75	2.89, 5.53	36.64, 139.01	1.97, 3.11	-19.43, 17.57		
	Min, Max	1.8, 7.0	-88.0, 248.7	1.2, 4.4	-31.8, 59.2		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Geometric Mean (CV%)	2.59 (53.29)		2.61 (25.09)		2.51 (27.82)	
	95% CI of Geometric Mean	2.13, 3.15		2.35, 2.90		2.03, 3.10	
	Median	2.32		2.67		2.70	
	Q25, Q75	2.16, 3.25		2.22, 2.82		1.94, 2.86	
	Min, Max	1.2, 14.7		1.4, 4.4		1.8, 4.2	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 3**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Geometric Mean (CV%)	3.76 (44.92)		2.21 (29.54)			
	95% CI of Geometric Mean	3.13, 4.51		1.90, 2.57			
	Mean (SD)		66.05 (89.537)		-12.93 (20.238)		
	95% CI		24.14, 107.96		-25.80, -0.07		
	Median	4.07	52.06	2.05	-12.93		
	Q25, Q75	2.54, 5.21	12.79, 99.44	1.94, 2.92	-21.73, -4.62		
	Min, Max	1.7, 7.9	-87.5, 341.5	1.3, 3.3	-59.7, 19.4		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Geometric Mean (CV%)	2.49 (49.23)		2.65 (25.77)		2.54 (32.92)	
	95% CI of Geometric Mean	2.11, 2.93		2.37, 2.96		1.81, 3.56	
	Median	2.30		2.68		2.53	
	Q25, Q75	1.81, 3.16		2.22, 2.84		1.88, 2.93	
	Min, Max	1.2, 14.7		1.4, 4.4		1.8, 4.2	

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.42.1 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 4**

Time Point	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Raw value	% Change(*)	Raw value	% Change(*)	Raw value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Geometric Mean (CV%)	3.87 (50.07)		2.19 (48.11)			
	95% CI of Geometric Mean	3.30, 4.54		1.74, 2.76			
	Mean (SD)		86.16 (134.924)		-11.08 (31.075)		
	95% CI		31.66, 140.66		-29.87, 7.70		
	Median	4.02	49.05	2.28	-16.09		
	Q25, Q75	2.83, 5.09	27.90, 103.74	1.49, 2.90	-33.53, 4.02		
	Min, Max	1.8, 13.6	-87.1, 647.3	0.9, 5.3	-46.5, 66.0		

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm

Note: Periods defined as Period 1 ([Day 1 – Day 6 confinement]), Period 2 ([Day 6 ambulatory – Day 30 Visit]), Period 3 ([Day 30 Visit – Day 60 Visit]) and Period 4 ([Day 60 Visit – Day 90 Visit]).

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**Table 15.2.4.43 Descriptive Statistics of 2-NA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	BLOQ, n (%)	2 (4.3)		1 (3.1)		1 (11.1)	
	Geometric Mean (CV%)	22.954 (86.9240)		20.513 (60.5858)		17.851 (87.2232)	
	95% CI of Geometric Mean	18.416, 28.611		16.767, 25.095		10.013, 31.826	
	Median	27.713		20.771		21.628	
	Q25, Q75	17.820, 36.479		14.339, 30.134		15.167, 28.943	
	Min, Max	1.46, 60.14		6.22, 62.92		3.21, 38.32	
	Mean (SD)	27.775 (13.9466)		23.794 (13.4461)		21.491 (11.0257)	
	95% CI of Mean	23.679, 31.870		18.946, 28.643		13.015, 29.966	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.43 Descriptive Statistics of 2-NA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	BLOQ, n (%)	35 (74.5)		2 (6.3)		6 (66.7)	
	Geometric Mean (CV%)	2.807 (71.6276)		16.716 (86.3068)		2.782 (75.8567)	
	95% CI of Geometric Mean	2.323, 3.392		12.773, 21.876		1.656, 4.672	
	Median	3.005	-89.502	18.614	-17.908	2.535	-83.534
	Q25, Q75	1.801, 3.698	-93.504, -80.564	11.180, 30.938	-38.901, 5.296	1.903, 3.549	-93.384, -69.640
	Min, Max	0.65, 31.98	-97.35, 114.50	1.85, 51.65	-90.94, 138.67	1.31, 11.99	-95.73, -20.96
	Mean (SD)	3.669 (4.5562)	-78.831 (34.9076)	20.803 (12.4411)	-7.151 (47.1879)	3.548 (3.2909)	-76.154 (24.1300)
	95% CI of Mean	2.331, 5.008	-89.081, -68.581	16.317, 25.289	-24.165, 9.862	1.018, 6.078	-94.702, -57.606

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	14.24	13.10	108.65 (20.69)
	95% CI	13.39, 15.14	11.99, 14.32	97.72, 120.80
Day 4	n	46	21	
	Geometric LS Mean (CV%)	14.89	12.90	115.49 (18.40)
	95% CI	14.10, 15.74	11.87, 14.02	104.74, 127.33
Day 30	n	25	17	
	Geometric LS Mean (CV%)	15.33	13.25	115.68 (24.24)
	95% CI	13.84, 16.99	11.75, 14.95	98.62, 135.70
Day 60	n	20	12	
	Geometric LS Mean (CV%)	15.58	12.84	121.34 (21.91)
	95% CI	13.97, 17.38	11.17, 14.75	100.82, 146.04
Day 90	n	26	13	
	Geometric LS Mean (CV%)	14.37	11.87	121.01 (36.92)
	95% CI	12.31, 16.77	9.64, 14.62	92.51, 158.27

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

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**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	707.50	598.76	118.16 (43.45)
	95% CI	625.04, 800.83	501.15, 715.38	95.40, 146.34
Day 4	n	46	21	
	Geometric LS Mean (CV%)	814.45	626.03	130.10 (34.42)
	95% CI	736.78, 900.31	538.41, 727.92	108.82, 155.54
Day 30	n	25	17	
	Geometric LS Mean (CV%)	770.79	666.86	115.58 (40.17)
	95% CI	653.37, 909.29	548.35, 810.98	89.07, 149.99
Day 60	n	20	12	
	Geometric LS Mean (CV%)	817.13	620.00	131.80 (39.93)
	95% CI	670.03, 996.52	481.41, 798.48	93.22, 186.32
Day 90	n	26	13	
	Geometric LS Mean (CV%)	670.32	558.67	119.98 (57.76)
	95% CI	531.86, 844.83	409.26, 762.61	80.26, 179.37

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

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**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	50.13	45.72	109.66 (34.45)
	95% CI	45.36, 55.40	39.60, 52.78	92.32, 130.25
Day 4	n	46	21	
	Geometric LS Mean (CV%)	54.90	48.74	112.64 (30.57)
	95% CI	50.19, 60.05	42.59, 55.78	96.03, 132.11
Day 30	n	25	17	
	Geometric LS Mean (CV%)	50.62	49.64	101.97 (29.34)
	95% CI	44.73, 57.27	42.94, 57.37	83.99, 123.80
Day 60	n	20	12	
	Geometric LS Mean (CV%)	53.58	46.89	114.27 (38.18)
	95% CI	44.33, 64.76	37.11, 59.25	82.99, 157.33
Day 90	n	26	13	
	Geometric LS Mean (CV%)	46.30	47.47	97.55 (38.83)
	95% CI	39.38, 54.44	38.18, 59.00	73.62, 129.25

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

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**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	1.91	1.63	116.57 (24.46)
	95% CI	1.77, 2.05	1.47, 1.82	102.98, 131.94
Day 4	n	46	21	
	Geometric LS Mean (CV%)	1.99	1.60	124.27 (24.37)
	95% CI	1.84, 2.14	1.43, 1.79	109.32, 141.26
Day 30	n	25	17	
	Geometric LS Mean (CV%)	1.94	1.62	120.12 (25.53)
	95% CI	1.73, 2.18	1.41, 1.85	100.16, 144.06
Day 60	n	20	12	
	Geometric LS Mean (CV%)	1.97	1.65	119.89 (24.03)
	95% CI	1.74, 2.24	1.41, 1.92	97.75, 147.05
Day 90	n	26	13	
	Geometric LS Mean (CV%)	1.80	1.55	115.61 (26.55)
	95% CI	1.60, 2.02	1.33, 1.82	94.74, 141.08

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

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**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	27.04	20.94	129.17 (39.42)
	95% CI	24.13, 30.30	17.77, 24.66	106.01, 157.38
Day 4	n	46	21	
	Geometric LS Mean (CV%)	29.25	20.18	144.93 (33.16)
	95% CI	26.55, 32.23	17.44, 23.36	121.90, 172.32
Day 30	n	25	17	
	Geometric LS Mean (CV%)	28.49	22.10	128.93 (40.25)
	95% CI	23.99, 33.83	18.01, 27.11	97.38, 170.71
Day 60	n	20	12	
	Geometric LS Mean (CV%)	31.07	20.33	152.85 (34.85)
	95% CI	26.03, 37.10	16.22, 25.49	111.88, 208.81
Day 90	n	26	13	
	Geometric LS Mean (CV%)	26.04	18.20	143.07 (55.18)
	95% CI	20.81, 32.58	13.47, 24.59	96.77, 211.52

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

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**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	27.37	29.24	93.58 (25.31)
	95% CI	25.40, 29.48	26.27, 32.55	82.27, 106.45
Day 4	n	46	21	
	Geometric LS Mean (CV%)	28.93	31.77	91.05 (21.69)
	95% CI	27.12, 30.85	28.84, 35.01	81.17, 102.13
Day 30	n	25	17	
	Geometric LS Mean (CV%)	28.25	30.42	92.85 (25.18)
	95% CI	25.34, 31.48	26.81, 34.52	78.20, 110.25
Day 60	n	20	12	
	Geometric LS Mean (CV%)	28.75	29.71	96.76 (34.80)
	95% CI	24.25, 34.09	24.04, 36.72	72.77, 128.67
Day 90	n	26	13	
	Geometric LS Mean (CV%)	26.28	32.53	80.80 (30.52)
	95% CI	23.10, 29.90	27.35, 38.69	64.58, 101.10

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

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**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	41.02	43.97	93.30 (26.25)
	95% CI	37.98, 44.31	39.35, 49.13	81.64, 106.61
Day 4	n	46	21	
	Geometric LS Mean (CV%)	43.16	47.62	90.64 (22.33)
	95% CI	40.40, 46.12	43.11, 52.61	80.55, 101.99
Day 30	n	25	17	
	Geometric LS Mean (CV%)	42.30	45.38	93.22 (26.81)
	95% CI	37.73, 47.43	39.70, 51.87	77.82, 111.66
Day 60	n	20	12	
	Geometric LS Mean (CV%)	41.74	44.22	94.38 (33.85)
	95% CI	35.35, 49.27	35.98, 54.35	71.49, 124.61
Day 90	n	26	13	
	Geometric LS Mean (CV%)	39.89	48.29	82.61 (31.80)
	95% CI	34.89, 45.61	40.33, 57.81	65.47, 104.25

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

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**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	234.92	290.43	80.89 (22.43)
	95% CI	219.72, 251.17	263.96, 319.54	72.01, 90.85
Day 4	n	46	21	
	Geometric LS Mean (CV%)	218.66	290.11	75.37 (28.99)
	95% CI	200.68, 238.26	255.09, 329.94	64.64, 87.88
Day 30	n	25	17	
	Geometric LS Mean (CV%)	194.32	307.30	63.23 (33.88)
	95% CI	168.81, 223.67	260.38, 362.67	50.72, 78.84
Day 60	n	20	12	
	Geometric LS Mean (CV%)	211.10	330.28	63.92 (40.26)
	95% CI	173.32, 257.12	258.54, 421.91	45.83, 89.14
Day 90	n	26	13	
	Geometric LS Mean (CV%)	188.16	305.92	61.51 (55.09)
	95% CI	150.71, 234.93	226.77, 412.70	41.79, 90.52

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

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**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	16.39	23.28	70.41 (29.51)
	95% CI	15.02, 17.88	20.48, 26.46	60.26, 82.26
Day 4	n	46	21	
	Geometric LS Mean (CV%)	14.64	23.27	62.93 (36.28)
	95% CI	13.17, 16.28	19.78, 27.37	51.90, 76.30
Day 30	n	25	17	
	Geometric LS Mean (CV%)	12.72	23.50	54.13 (37.07)
	95% CI	10.91, 14.83	19.61, 28.16	42.58, 68.80
Day 60	n	20	12	
	Geometric LS Mean (CV%)	13.83	25.04	55.21 (47.12)
	95% CI	11.01, 17.36	18.92, 33.15	37.82, 80.59
Day 90	n	26	13	
	Geometric LS Mean (CV%)	13.31	26.63	49.97 (57.26)
	95% CI	10.57, 16.74	19.51, 36.33	33.46, 74.62

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

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**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	265.14	313.64	84.54 (20.17)
	95% CI	249.66, 281.57	287.81, 341.79	76.16, 93.83
Day 4	n	46	21	
	Geometric LS Mean (CV%)	251.43	312.59	80.43 (25.35)
	95% CI	233.18, 271.11	279.21, 349.96	70.30, 92.03
Day 30	n	25	17	
	Geometric LS Mean (CV%)	226.44	331.65	68.28 (30.04)
	95% CI	199.74, 256.70	286.16, 384.38	56.10, 83.09
Day 60	n	20	12	
	Geometric LS Mean (CV%)	246.29	356.86	69.02 (32.33)
	95% CI	209.70, 289.26	292.21, 435.80	52.58, 90.59
Day 90	n	26	13	
	Geometric LS Mean (CV%)	220.72	325.67	67.77 (49.51)
	95% CI	180.37, 270.09	248.01, 427.64	47.68, 96.33

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

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**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	1739.68	1636.12	106.33 (54.25)
	95% CI	1495.43, 2023.83	1315.93, 2034.20	81.85, 138.14
Day 4	n	46	21	
	Geometric LS Mean (CV%)	2143.60	1851.14	115.80 (38.92)
	95% CI	1915.51, 2398.85	1562.92, 2192.52	94.76, 141.51
Day 30	n	25	17	
	Geometric LS Mean (CV%)	2117.36	1697.72	124.72 (42.48)
	95% CI	1775.63, 2524.86	1382.00, 2085.57	94.53, 164.53
Day 60	n	20	12	
	Geometric LS Mean (CV%)	2402.99	1634.04	147.06 (40.82)
	95% CI	1971.63, 2928.73	1277.75, 2089.67	105.55, 204.89
Day 90	n	26	13	
	Geometric LS Mean (CV%)	2102.07	1809.20	116.19 (56.01)
	95% CI	1677.53, 2634.04	1335.63, 2450.67	78.45, 172.08

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

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**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	122.49	129.49	94.60 (47.15)
	95% CI	107.18, 139.98	106.65, 157.22	74.95, 119.39
Day 4	n	46	21	
	Geometric LS Mean (CV%)	144.71	146.54	98.75 (38.98)
	95% CI	129.28, 161.97	123.58, 173.76	80.73, 120.79
Day 30	n	25	17	
	Geometric LS Mean (CV%)	138.46	130.16	106.38 (37.56)
	95% CI	118.42, 161.89	108.22, 156.54	83.05, 136.26
Day 60	n	20	12	
	Geometric LS Mean (CV%)	153.81	127.57	120.57 (46.82)
	95% CI	122.86, 192.56	96.22, 169.15	82.44, 176.32
Day 90	n	26	13	
	Geometric LS Mean (CV%)	146.87	153.42	95.73 (43.94)
	95% CI	122.45, 176.17	120.05, 196.06	69.66, 131.56

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

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**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	209.92	243.49	86.21 (26.32)
	95% CI	194.28, 226.81	217.71, 272.32	75.32, 98.68
Day 4	n	46	21	
	Geometric LS Mean (CV%)	230.56	261.91	88.03 (22.23)
	95% CI	215.86, 246.26	237.13, 289.28	78.24, 99.04
Day 30	n	25	17	
	Geometric LS Mean (CV%)	245.61	224.00	109.64 (26.60)
	95% CI	218.55, 276.01	195.09, 257.20	90.57, 132.74
Day 60	n	20	12	
	Geometric LS Mean (CV%)	265.20	227.66	116.49 (34.79)
	95% CI	222.16, 316.58	181.77, 285.14	85.30, 159.08
Day 90	n	26	13	
	Geometric LS Mean (CV%)	273.11	278.84	97.94 (29.51)
	95% CI	241.07, 309.41	235.66, 329.94	78.78, 121.77

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

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**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	338.26	389.11	86.93 (27.65)
	95% CI	311.92, 366.82	346.05, 437.54	75.47, 100.13
Day 4	n	46	21	
	Geometric LS Mean (CV%)	372.03	417.15	89.18 (23.60)
	95% CI	346.96, 398.91	375.48, 463.44	78.73, 101.03
Day 30	n	25	17	
	Geometric LS Mean (CV%)	397.50	361.54	109.95 (27.65)
	95% CI	352.61, 448.10	313.83, 416.49	90.55, 133.50
Day 60	n	20	12	
	Geometric LS Mean (CV%)	421.52	372.85	113.05 (36.82)
	95% CI	350.21, 507.34	294.54, 471.97	81.72, 156.39
Day 90	n	26	13	
	Geometric LS Mean (CV%)	458.30	435.54	105.23 (31.34)
	95% CI	401.48, 523.15	364.25, 520.78	83.48, 132.64

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

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**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	2.80	1.97	141.69 (47.58)
	95% CI	2.44, 3.21	1.62, 2.40	112.14, 179.02
Day 4	n	46	21	
	Geometric LS Mean (CV%)	3.34	2.10	158.82 (45.38)
	95% CI	2.93, 3.81	1.72, 2.56	125.96, 200.27
Day 30	n	25	17	
	Geometric LS Mean (CV%)	3.42	2.08	164.17 (47.37)
	95% CI	2.81, 4.15	1.66, 2.61	121.54, 221.74
Day 60	n	20	12	
	Geometric LS Mean (CV%)	3.22	1.89	170.43 (61.28)
	95% CI	2.42, 4.29	1.32, 2.70	105.89, 274.31
Day 90	n	26	13	
	Geometric LS Mean (CV%)	3.05	1.76	173.94 (71.18)
	95% CI	2.31, 4.03	1.21, 2.55	107.57, 281.24

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

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**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	10.59	7.05	150.34 (46.79)
	95% CI	9.26, 12.12	5.81, 8.54	119.01, 189.92
Day 4	n	46	21	
	Geometric LS Mean (CV%)	12.02	6.90	174.14 (48.64)
	95% CI	10.46, 13.82	5.60, 8.51	135.84, 223.23
Day 30	n	25	17	
	Geometric LS Mean (CV%)	12.17	7.19	169.18 (51.20)
	95% CI	9.88, 14.98	5.62, 9.20	121.73, 235.10
Day 60	n	20	12	
	Geometric LS Mean (CV%)	11.62	6.69	173.58 (64.82)
	95% CI	8.62, 15.66	4.62, 9.70	105.37, 285.94
Day 90	n	26	13	
	Geometric LS Mean (CV%)	12.11	5.52	219.21 (65.11)
	95% CI	9.34, 15.69	3.90, 7.82	139.63, 344.15

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

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**Table 15.2.4.43.1 Analysis of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)**

Time Point	Statistic	THSm2.2	mCC	THSm2.2 : mCC ratio
Day 1	n	47	23	
	Geometric LS Mean (CV%)	3.37	2.63	128.46 (29.40)
	95% CI	3.09, 3.68	2.31, 2.98	110.51, 149.33
Day 4	n	46	21	
	Geometric LS Mean (CV%)	3.68	2.66	138.65 (34.61)
	95% CI	3.32, 4.08	2.27, 3.10	115.68, 166.18
Day 30	n	25	17	
	Geometric LS Mean (CV%)	4.17	2.46	169.43 (33.88)
	95% CI	3.62, 4.81	2.08, 2.91	135.83, 211.34
Day 60	n	20	12	
	Geometric LS Mean (CV%)	3.82	2.30	165.84 (40.16)
	95% CI	3.13, 4.66	1.80, 2.94	119.11, 230.90
Day 90	n	26	13	
	Geometric LS Mean (CV%)	3.93	2.26	174.02 (51.79)
	95% CI	3.18, 4.85	1.70, 3.00	120.77, 250.74

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Appendix: 15.3.7.1

Study ID: ZRHM-REXA-08-US

Program: t1502044301_ZRHM-REXA-08_US_v1_PMI.sas

Status: Final v1.0/21DEC2015

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**Table 15.2.4.44 Descriptive Statistics of o-tol (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	BLOQ, n (%)	10 (21.3)		13 (40.6)		2 (22.2)	
	Geometric Mean (CV%)	131.88 (64.928)		125.74 (58.733)		108.76 (51.236)	
	95% CI of Geometric Mean	110.80, 156.97		103.33, 153.01		75.03, 157.63	
	Median	143.17		121.21		93.70	
	Q25, Q75	101.18, 199.07		81.71, 177.73		75.32, 147.64	
	Min, Max	29.1, 404.5		51.0, 390.0		61.7, 234.0	
	Mean (SD)	152.58 (76.249)		146.38 (88.971)		121.02 (61.426)	
	95% CI of Mean	130.19, 174.98		114.30, 178.46		73.80, 168.25	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.44 Descriptive Statistics of o-tol (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	BLOQ, n (%)	37 (78.7)		9 (28.1)		6 (66.7)	
	Geometric Mean (CV%)	50.26 (71.496)		106.90 (69.157)		47.81 (43.148)	
	95% CI of Geometric Mean	41.61, 60.70		85.32, 133.93		34.79, 65.68	
	Median	59.52	-63.55	107.02	-11.94	50.71	-57.28
	Q25, Q75	34.20, 68.49	-81.72, -28.86	64.72, 173.74	-39.55, 12.52	38.05, 65.65	-72.28, -35.76
	Min, Max	13.0, 535.8	-89.4, 202.0	31.6, 387.2	-83.4, 333.7	24.5, 71.2	-74.5, 2.4
	Mean (SD)	64.85 (75.692)	-47.27 (52.711)	128.84 (83.005)	2.20 (75.030)	51.22 (18.362)	-50.19 (27.019)
	95% CI of Mean	42.62, 87.08	-62.75, -31.79	98.91, 158.78	-24.85, 29.26	37.10, 65.34	-70.97, -29.42

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.45 Descriptive Statistics of CEMA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Geometric Mean (CV%)	97.208 (75.0176)		88.527 (59.1251)		91.515 (92.7522)	
	95% CI of Geometric Mean	79.891, 118.278		72.668, 107.848		49.943, 167.690	
	Median	122.605		88.862		109.458	
	Q25, Q75	67.956, 157.078		61.779, 126.580		102.765, 116.279	
	Min, Max	8.02, 265.33		25.77, 289.50		11.87, 180.46	
	Mean (SD)	115.368 (59.4853)		102.079 (57.5409)		108.289 (44.0499)	
	95% CI of Mean	97.902, 132.834		81.333, 122.825		74.429, 142.149	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.45 Descriptive Statistics of CEMA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	Geometric Mean (CV%)	10.368 (122.0547)		76.473 (75.8240)		11.045 (181.1087)	
	95% CI of Geometric Mean	7.832, 13.724		59.976, 97.508		4.371, 27.906	
	Median	9.464	-89.166	83.296	-3.768	11.076	-84.688
	Q25, Q75	5.106, 15.541	-95.624, -76.746	54.211, 121.439	-36.772, 16.302	5.294, 22.365	-96.123, -76.712
	Min, Max	0.81, 144.44	-98.18, 10.15	11.45, 214.42	-63.40, 107.37	1.73, 102.48	-98.46, -6.70
	Mean (SD)	16.956 (23.3854)	-82.253 (22.3686)	92.256 (52.9488)	-5.046 (41.6579)	21.635 (31.4078)	-75.109 (30.7854)
	95% CI of Mean	10.089, 23.822	-88.821, -75.685	73.165, 111.346	-20.066, 9.973	-2.508, 45.778	-98.774, -51.445

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.46 Descriptive Statistics of HEMA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Geometric Mean (CV%)	3312.2 (120.76)		3307.5 (94.28)		3426.6 (61.01)	
	95% CI of Geometric Mean	2507.2, 4375.8		2481.0, 4409.4		2223.8, 5280.0	
	Median	3139.9		3649.2		2848.0	
	Q25, Q75	1619.0, 6387.9		2033.6, 5301.9		2765.0, 4780.5	
	Min, Max	477, 27500		453, 12979		1274, 8883	
	Mean (SD)	5152.9 (5586.83)		4316.5 (3059.87)		3946.8 (2328.79)	
	95% CI of Mean	3512.5, 6793.3		3213.2, 5419.7		2156.7, 5736.9	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.46 Descriptive Statistics of HEMA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	BLOQ, n (%)	1 (2.1)		0		0	
	Geometric Mean (CV%)	1052.5 (77.16)		2462.5 (104.40)		1017.8 (74.45)	
	95% CI of Geometric Mean	861.1, 1286.4		1806.9, 3356.0		610.9, 1695.7	
	Median	1017.4	-71.6	2730.1	-22.3	1061.1	-73.4
	Q25, Q75	714.3, 1779.7	-78.6, -50.9	1504.7, 3989.0	-47.3, 2.4	664.7, 1689.4	-76.7, -66.3
	Min, Max	125, 4254	-97, 70	336, 22746	-79, 161	339, 2515	-83, -33
	Mean (SD)	1300.2 (863.97)	-59.8 (30.35)	3517.9 (3947.93)	-13.4 (51.91)	1219.1 (728.12)	-66.8 (18.02)
	95% CI of Mean	1046.4, 1553.9	-68.7, -50.8	2094.5, 4941.4	-32.2, 5.3	659.3, 1778.8	-80.7, -52.9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.47 Descriptive Statistics of B[a]P (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	46		32		9	
	Missing, n(%)	1 (2.1)		0		0	
	BLOQ, n (%)	2 (4.3)		4 (12.5)		0	
	Geometric Mean (CV%)	160.37 (65.882)		120.42 (76.978)		97.23 (57.083)	
	95% CI of Geometric Mean	134.18, 191.68		94.16, 154.00		64.64, 146.25	
	Median	176.56		142.18		82.34	
	Q25, Q75	121.71, 253.52		86.73, 182.40		74.81, 127.69	
	Min, Max	47.9, 465.1		27.5, 335.5		37.8, 202.3	
	Mean (SD)	187.65 (99.476)		146.66 (86.615)		109.62 (55.826)	
	95% CI of Mean	158.11, 217.20		115.43, 177.89		66.70, 152.54	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.47 Descriptive Statistics of B[a]P (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	46	32	32	9	9
	Missing, n(%)	0	1 (2.1)	0	0	0	0
	BLOQ, n (%)	21 (44.7)		6 (18.8)		4 (44.4)	
	Geometric Mean (CV%)	50.96 (96.104)		90.01 (88.564)		32.35 (61.656)	
	95% CI of Geometric Mean	40.18, 64.62		68.41, 118.44		20.90, 50.04	
	Median	44.80	-70.26	102.13	-27.11	35.21	-61.87
	Q25, Q75	30.05, 79.72	-80.62, -48.89	49.06, 151.18	-49.49, -3.30	20.12, 46.56	-75.10, -46.75
	Min, Max	11.5, 328.4	-97.5, 205.8	18.6, 293.7	-73.7, 206.3	13.2, 69.5	-89.6, -43.4
	Mean (SD)	72.25 (70.881)	-54.57 (49.705)	115.22 (75.817)	-13.33 (55.797)	37.12 (20.184)	-62.34 (16.953)
	95% CI of Mean	51.43, 93.07	-69.33, -39.80	87.88, 142.56	-33.45, 6.80	21.60, 52.64	-75.37, -49.30

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.48 Descriptive Statistics of HMPMA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	BLOQ, n (%)	0		1 (3.1)		0	
	Geometric Mean (CV%)	321.04 (66.513)		262.93 (66.355)		249.76 (63.823)	
	95% CI of Geometric Mean	268.77, 383.48		211.47, 326.91		159.36, 391.44	
	Median	331.93		265.31		253.81	
	Q25, Q75	212.24, 494.66		177.54, 401.79		225.29, 349.61	
	Min, Max	91.4, 945.9		49.8, 964.8		62.6, 513.2	
	Mean (SD)	379.19 (216.256)		309.88 (184.602)		281.23 (122.773)	
	95% CI of Mean	315.69, 442.69		243.32, 376.44		186.85, 375.60	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.48 Descriptive Statistics of HMPMA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	BLOQ, n (%)	8 (17.0)		1 (3.1)		1 (11.1)	
	Geometric Mean (CV%)	66.58 (74.919)		247.57 (85.754)		85.39 (120.215)	
	95% CI of Geometric Mean	54.72, 80.99		189.43, 323.56		41.28, 176.64	
	Median	58.89	-82.26	300.12	-7.76	72.26	-67.31
	Q25, Q75	36.52, 98.31	-88.20, -66.73	155.54, 372.86	-37.37, 37.69	46.08, 114.29	-88.51, -65.24
	Min, Max	23.8, 385.3	-96.8, 178.0	27.9, 1299.9	-67.8, 275.1	28.5, 529.8	-91.9, 746.8
	Mean (SD)	86.06 (78.120)	-63.28 (49.627)	315.69 (239.905)	17.59 (88.564)	135.22 (162.368)	22.00 (273.231)
	95% CI of Mean	63.12, 109.00	-77.86, -48.71	229.19, 402.19	-14.34, 49.53	10.41, 260.03	-188.03, 232.02

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.49 Descriptive Statistics of S-BMA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Geometric Mean (CV%)	3745.6 (86.16)		3430.9 (84.78)		4049.0 (89.41)	
	95% CI of Geometric Mean	3009.5, 4661.6		2631.3, 4473.5		2246.3, 7298.1	
	Median	3579.9		3190.7		3708.8	
	Q25, Q75	2494.8, 5295.6		2076.6, 6033.2		2395.3, 7119.2	
	Min, Max	856, 50971		809, 14301		1326, 14086	
	Mean (SD)	5473.4 (8158.51)		4479.8 (3536.38)		5259.2 (4155.97)	
	95% CI of Mean	3077.9, 7868.8		3204.8, 5754.9		2064.6, 8453.8	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.49 Descriptive Statistics of S-BMA (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	Geometric Mean (CV%)	3416.4 (91.94)		2833.2 (90.51)		3529.0 (73.56)	
	95% CI of Geometric Mean	2715.0, 4299.1		2143.6, 3744.6		2128.7, 5850.2	
	Median	2979.3	-10.8	2404.2	-11.4	2833.3	1.6
	Q25, Q75	1991.5, 4972.5	-42.8, 28.8	1931.2, 4279.3	-59.2, 48.4	2552.7, 4709.9	-33.8, 17.6
	Min, Max	979, 42886	-92, 785	624, 32887	-88, 951	1534, 15740	-69, 133
	Mean (SD)	5076.1 (7006.64)	31.8 (152.38)	4115.5 (5658.86)	30.7 (184.26)	4505.2 (4340.51)	6.7 (68.40)
	95% CI of Mean	3018.8, 7133.3	-13.0, 76.6	2075.2, 6155.8	-35.8, 97.2	1168.8, 7841.7	-45.9, 59.4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.50 Descriptive Statistics of NEQ (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		31		9	
	Missing, n(%)	0		1 (3.1)		0	
	BLOQ, n (%)	9 (19.1)		5 (16.1)		0	
	Geometric Mean (CV%)	7.9505 (78.93015)		8.3231 (63.23396)		7.0552 (66.69200)	
	95% CI of Geometric Mean	0.6481, 97.5290		0.6728, 102.9620		0.4425, 112.4630	
	Median	10.0586		7.4951		8.1395	
	Q25, Q75	5.9251, 12.3714		5.2798, 12.8882		6.3640, 11.0073	
	Min, Max	0.461, 18.260		2.681, 21.289		2.458, 15.660	
	Mean (SD)	9.3550 (4.27357)		9.7447 (5.57475)		8.1448 (4.20193)	
	95% CI of Mean	8.1002, 10.6098		7.6998, 11.7895		4.9149, 11.3747	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.50 Descriptive Statistics of NEQ (pg/mg creat) in 4-hour Urine Fraction - PP Set****Product Use Time Period: Period 4**

Time-point	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	31	9	9
	Missing, n(%)	0	0	0	1 (3.1)	0	0
	BLOQ, n (%)	8 (17.0)		5 (15.6)		8 (88.9)	
	Geometric Mean (CV%)	6.6237 (82.52153)		7.5019 (63.21211)		0.5863 (380.24106)	
	95% CI of Geometric Mean	0.5360, 81.8460		0.6086, 92.4610		0.0164, 20.9170	
	Median	8.2861	-14.1265	7.3635	-16.1283	0.8962	-76.6099
	Q25, Q75	4.9185, 10.6744	-37.8500, 0.0000	5.3167, 12.7168	-30.2946, 16.2889	0.2434, 1.9038	-97.7885, -63.5315
	Min, Max	0.418, 16.401	-66.983, 174.338	1.824, 17.815	-40.089, 81.496	0.024, 3.448	-99.845, -58.158
	Mean (SD)	7.9367 (3.79359)	-6.8943 (53.08637)	8.7042 (4.56890)	-5.3256 (29.72838)	1.2397 (1.16095)	-79.7445 (16.99388)
	95% CI of Mean	6.8229, 9.0506	-22.4811, 8.6925	7.0569, 10.3515	-16.2301, 5.5789	0.3473, 2.1321	-92.8072, -66.6818

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.51.1 Descriptive Statistics of Fagerstrom Test for Nicotine Dependence Results - PP Set****Parameter: Fagerstrom score****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾
Baseline	n	47		32		9	
	Mean (SD)	5.83 (2.220)		5.63 (1.700)		5.89 (2.369)	
	Median	6.00		6.00		6.00	
	Q25, Q75	4.00, 7.00		4.50, 7.00		4.00, 8.00	
	Min, Max	1.0, 10.0		1.0, 9.0		2.0, 8.0	
	Mild (0 - 3), n(%)	7 (14.9)		3 (9.4)		2 (22.2)	
	Moderate (4 - 6), n(%)	19 (40.4)		20 (62.5)		3 (33.3)	
	Severe (7 - 10), n(%)	21 (44.7)		9 (28.1)		4 (44.4)	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: [1] %change/shift from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.51.1 Descriptive Statistics of Fagerstrom Test for Nicotine Dependence Results - PP Set****Parameter: Fagerstrom score****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾
Day 90	n	46	46	27	27	4	4
	Missing, n(%)	1(2.1)	1(2.1)	5(15.6)	5(15.6)	5(55.6)	5(55.6)
	Mean (SD)	5.00 (2.310)	-0.83 (1.717)	4.93 (1.839)	-0.63 (2.022)	1.50 (1.291)	-2.75 (2.987)
	Median	5.00	-1.00	5.00	-1.00	1.50	-2.00
	Q25, Q75	3.00, 7.00	-2.00, 0.00	4.00, 6.00	-2.00, 1.00	0.50, 2.50	-4.50, -1.00
	Min, Max	1.0, 9.0	-4.0, 4.0	2.0, 9.0	-4.0, 3.0	0.0, 3.0	-7.0, 0.0
	Mild (0 - 3), n(%)	14 (29.8)		5 (15.6)		4 (44.4)	
	Moderate to Mild, n(%)		9 (19.1)		4 (12.5)		1 (11.1)
	Severe to Mild, n(%)						1 (11.1)
	Moderate (4 - 6), n(%)	20 (42.6)		18 (56.3)			
	Mild to Moderate, n(%)		2 (4.3)		2 (6.3)		
	Severe to Moderate, n(%)		11 (23.4)		6 (18.8)		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: [1] %change/shift from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.51.1 Descriptive Statistics of Fagerstrom Test for Nicotine Dependence Results - PP Set****Parameter: Fagerstrom score****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾
Day 90	Severe (7 - 10), n(%)	12 (25.5)		4 (12.5)			
	Moderate to Severe, n(%)		2 (4.3)		2 (6.3)		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: [1] %change/shift from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

Appendix 15.3.6.13

Study ID: ZRHM-REXA-08-US

Program: t_fager_pp.sas

Status: Final

21SEP15

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**Table 15.2.4.51.2 Descriptive Statistics of Fagerstrom Test for Nicotine Dependence Results - FAS****Parameter: Fagerstrom score**

		THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
Timepoint	Statistic	Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾
Baseline	n	80		39		39	
	Missing, n(%)	0		2(4.9)		0	
	Mean (SD)	5.61 (2.248)		5.54 (1.668)		5.72 (2.140)	
	Median	6.00		6.00		6.00	
	Q25, Q75	4.00, 7.00		4.00, 7.00		4.00, 8.00	
	Min, Max	0.0, 10.0		1.0, 9.0		2.0, 9.0	
	Mild (0 - 3), n(%)	14 (17.5)		4 (9.8)		7 (17.9)	
	Moderate (4 - 6), n(%)	35 (43.8)		25 (61.0)		18 (46.2)	
	Severe (7 - 10), n(%)	31 (38.8)		10 (24.4)		14 (35.9)	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: [1] %change/shift from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.51.2 Descriptive Statistics of Fagerstrom Test for Nicotine Dependence Results - FAS****Parameter: Fagerstrom score**

		THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
Timepoint	Statistic	Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾
Day 90	n	71	71	31	30	26	26
	Missing, n(%)	9(11.3)	9(11.3)	10(24.4)	11(26.8)	13(33.3)	13(33.3)
	Mean (SD)	4.92 (2.389)	-0.73 (1.898)	4.94 (1.949)	-0.53 (2.209)	3.04 (2.218)	-2.27 (2.920)
	Median	5.00	0.00	5.00	-1.00	3.00	-2.00
	Q25, Q75	3.00, 7.00	-2.00, 1.00	4.00, 6.00	-2.00, 1.00	2.00, 5.00	-4.00, 0.00
	Min, Max	0.0, 9.0	-4.0, 5.0	2.0, 9.0	-4.0, 4.0	0.0, 7.0	-9.0, 5.0
	Mild (0 - 3), n(%)	23 (28.8)		6 (14.6)		18 (46.2)	
	Moderate to Mild, n(%)		12 (15.0)		5 (12.2)		9 (23.1)
	Severe to Mild, n(%)		2 (2.5)				4 (10.3)
	Moderate (4 - 6), n(%)	28 (35.0)		20 (48.8)		5 (12.8)	
	Mild to Moderate, n(%)		3 (3.8)		2 (4.9)		
	Severe to Moderate, n(%)		13 (16.3)		6 (14.6)		3 (7.7)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: [1] %change/shift from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.51.2 Descriptive Statistics of Fagerstrom Test for Nicotine Dependence Results - FAS****Parameter: Fagerstrom score**

		THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
Timepoint	Statistic	Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾
Day 90	Severe (7 - 10), n(%)	20 (25.0)		5 (12.2)		3 (7.7)	
	Mild to Severe, n(%)		1 (1.3)				1 (2.6)
	Moderate to Severe, n(%)		5 (6.3)		3 (7.3)		1 (2.6)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: [1] %change/shift from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.



**Table 15.2.4.51.3 Descriptive Statistics of Fagerstrom Test for Nicotine Dependence
Results - Compliant Population**

Parameter: Fagerstrom score
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=41)		mCC (N=31)		SA (N=7)	
		Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾
Baseline	n	41		31		7	
	Mean (SD)	6.00 (2.214)		5.61 (1.726)		5.29 (2.361)	
	Median	6.00		6.00		6.00	
	Q25, Q75	4.00, 8.00		4.00, 7.00		3.00, 8.00	
	Min, Max	1.0, 10.0		1.0, 9.0		2.0, 8.0	
	Mild (0 - 3), n(%)	5 (12.2)		3 (9.7)		2 (28.6)	
	Moderate (4 - 6), n(%)	17 (41.5)		19 (61.3)		3 (42.9)	
	Severe (7 - 10), n(%)	19 (46.3)		9 (29.0)		2 (28.6)	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: [1] %change/shift from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.



**Table 15.2.4.51.3 Descriptive Statistics of Fagerstrom Test for Nicotine Dependence
Results - Compliant Population**

Parameter: Fagerstrom score
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=41)		mCC (N=31)		SA (N=7)	
		Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾
Day 90	n	40	40	27	27	4	4
	Missing, n(%)	1(2.4)	1(2.4)	4(12.9)	4(12.9)	3(42.9)	3(42.9)
	Mean (SD)	5.18 (2.374)	-0.83 (1.709)	4.93 (1.839)	-0.63 (2.022)	1.50 (1.291)	-2.75 (2.987)
	Median	5.00	-1.00	5.00	-1.00	1.50	-2.00
	Q25, Q75	3.00, 7.00	-2.00, 0.00	4.00, 6.00	-2.00, 1.00	0.50, 2.50	-4.50, -1.00
	Min, Max	1.0, 9.0	-4.0, 4.0	2.0, 9.0	-4.0, 3.0	0.0, 3.0	-7.0, 0.0
	Mild (0 - 3), n(%)	11 (26.8)		5 (16.1)		4 (57.1)	
	Moderate to Mild, n(%)		7 (17.1)		4 (12.9)		1 (14.3)
	Severe to Mild, n(%)						1 (14.3)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: [1] %change/shift from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.



**Table 15.2.4.51.3 Descriptive Statistics of Fagerstrom Test for Nicotine Dependence
Results - Compliant Population**

Parameter: Fagerstrom score
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=41)		mCC (N=31)		SA (N=7)	
		Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾	Value	Change/ Shift ⁽¹⁾
Day 90	Moderate (4 - 6), n(%)	17 (41.5)		18 (58.1)		0 (0.0)	
	Mild to Moderate, n(%)		1 (2.4)		2 (6.5)		
	Severe to Moderate, n(%)		9 (22.0)		6 (19.4)		
	Severe (7 - 10), n(%)	12 (29.3)		4 (12.9)		0 (0.0)	
	Moderate to Severe, n(%)		2 (4.9)		2 (6.5)		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: [1] %change/shift from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Mean (SD)	4.80 (1.718)		4.78 (2.041)		4.73 (1.659)	
	95% CI of Mean	4.40, 5.20		4.07, 5.48		4.02, 5.43	
	Median	4.80		5.60		4.90	
	Q25, Q75	3.60, 6.40		3.20, 6.60		3.50, 5.90	
	Min, Max	1.0, 7.0		1.0, 7.0		1.4, 7.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	75	75	33	33	24	24
	Missing, n(%)	0	0	2 (5.7)	2 (5.7)	0	0
	Mean (SD)	4.51 (1.844)	5.71 (61.639)	4.56 (1.926)	27.91 (128.508)	5.85 (1.228)	48.57 (97.932)
	95% CI of Mean	4.08, 4.94	-8.48, 19.90	3.88, 5.25	-17.66, 73.48	5.33, 6.37	7.21, 89.93
	Median	4.60	0.00	4.60	0.00	6.10	11.27
	Q25, Q75	3.00, 6.20	-21.43, 11.11	3.00, 6.20	-16.67, 16.67	5.50, 6.90	-1.43, 55.00
	Min, Max	1.0, 7.0	-85.7, 337.5	1.0, 7.0	-84.4, 580.0	2.6, 7.0	-39.3, 400.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	4.41 (1.793)	8.30 (80.846)	4.46 (2.008)	23.61 (110.283)	5.38 (1.725)	38.73 (97.217)
	95% CI of Mean	3.99, 4.83	-10.30, 26.91	3.76, 5.17	-14.87, 62.09	4.64, 6.11	-2.33, 79.78
	Median	4.20	-3.03	4.60	0.00	6.40	0.00
	Q25, Q75	3.20, 5.80	-27.27, 11.54	2.80, 6.20	-33.33, 45.83	4.00, 6.60	-16.64, 80.56
	Min, Max	1.0, 7.0	-85.7, 380.0	1.0, 7.0	-85.7, 460.0	2.0, 7.0	-64.3, 357.1

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	75	75	34	34	23	23
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Mean (SD)	4.45 (1.665)	7.49 (75.304)	4.26 (2.070)	8.43 (91.378)	4.67 (1.911)	22.91 (83.662)
	95% CI of Mean	4.07, 4.84	-9.84, 24.82	3.54, 4.99	-23.46, 40.32	3.84, 5.50	-13.28, 59.09
	Median	4.40	-5.88	4.00	-1.61	5.20	0.00
	Q25, Q75	3.20, 6.00	-27.27, 12.00	2.00, 6.00	-19.05, 7.14	3.80, 6.00	-21.43, 75.00
	Min, Max	1.0, 7.0	-85.7, 400.0	1.0, 7.0	-84.4, 480.0	1.0, 7.0	-85.7, 242.9

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	4.40 (1.782)	3.93 (72.012)	4.62 (2.092)	32.17 (138.485)	4.58 (1.891)	16.61 (84.416)
	95% CI of Mean	3.99, 4.81	-12.64, 20.51	3.88, 5.35	-16.15, 80.50	3.78, 5.39	-19.04, 52.26
	Median	4.40	-4.35	5.20	0.00	5.00	0.00
	Q25, Q75	3.20, 6.00	-22.22, 5.26	2.40, 6.60	-14.29, 25.00	3.30, 6.00	-32.86, 32.14
	Min, Max	1.0, 7.0	-85.7, 400.0	1.0, 7.0	-85.7, 600.0	1.0, 7.0	-75.0, 300.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	4.39 (1.803)	-0.10 (57.335)	4.24 (1.987)	11.81 (88.631)	4.79 (2.208)	21.19 (99.412)
	95% CI of Mean	3.97, 4.81	-13.29, 13.10	3.54, 4.93	-19.12, 42.74	3.85, 5.73	-20.79, 63.18
	Median	4.20	-9.09	4.10	0.00	5.40	0.00
	Q25, Q75	3.20, 6.00	-28.57, 18.18	2.40, 6.00	-10.00, 12.50	3.40, 7.00	-13.19, 27.38
	Min, Max	1.0, 7.0	-78.3, 337.5	1.0, 7.0	-85.7, 420.0	1.0, 7.0	-82.1, 400.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34		13	
	Mean (SD)	5.15 (1.666)		4.61 (2.048)		5.40 (1.327)	
	95% CI of Mean	4.61, 5.69		3.89, 5.33		4.59, 6.21	
	Median	5.40		4.90		5.80	
	Q25, Q75	4.20, 6.60		2.80, 6.40		4.60, 6.20	
	Min, Max	1.0, 7.0		1.0, 7.0		3.2, 7.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	39	39	32	32	13	13
	Missing, n(%)	1 (2.5)	1 (2.5)	2 (5.9)	2 (5.9)	0	0
	Mean (SD)	4.75 (1.397)	-1.65 (38.429)	4.51 (1.769)	16.96 (74.060)	3.18 (1.655)	-37.44 (35.717)
	95% CI of Mean	4.29, 5.21	-14.11, 10.81	3.87, 5.15	-9.75, 43.66	2.18, 4.19	-59.03, -15.85
	Median	4.60	-5.88	5.10	-4.46	3.40	-39.29
	Q25, Q75	4.00, 6.00	-23.53, 10.34	3.00, 6.00	-24.94, 37.50	1.80, 4.40	-74.29, -4.35
	Min, Max	2.0, 7.0	-71.4, 100.0	1.6, 7.0	-71.4, 280.0	1.0, 6.0	-80.0, 17.6

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35		12	
	Mean (SD)	5.14 (1.537)		4.67 (2.057)		5.20 (1.233)	
	95% CI of Mean	4.64, 5.64		3.96, 5.39		4.41, 5.99	
	Median	5.20		5.00		5.40	
	Q25, Q75	4.00, 6.60		2.80, 6.60		4.30, 5.90	
	Min, Max	1.0, 7.0		1.0, 7.0		3.2, 7.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	32	32	11	11
	Missing, n(%)	0	0	3 (8.6)	3 (8.6)	1 (8.3)	1 (8.3)
	Mean (SD)	4.98 (1.383)	6.83 (51.641)	5.14 (1.622)	34.34 (104.877)	3.02 (1.808)	-40.27 (42.149)
	95% CI of Mean	4.53, 5.43	-9.92, 23.57	4.55, 5.73	-3.48, 72.16	1.80, 4.24	-68.59, -11.95
	Median	5.00	0.00	5.60	1.52	2.80	-41.38
	Q25, Q75	4.00, 6.00	-15.38, 17.39	4.00, 6.80	-8.10, 47.32	1.20, 4.60	-75.00, -32.14
	Min, Max	1.0, 7.0	-70.6, 240.0	1.4, 7.0	-80.0, 480.0	1.0, 6.0	-80.0, 66.7

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	4.99 (1.557)		4.73 (2.045)		4.80 (1.049)	
	95% CI of Mean	4.53, 5.45		3.98, 5.47		3.99, 5.61	
	Median	5.00		5.30		4.60	
	Q25, Q75	4.00, 6.40		3.00, 6.50		4.00, 5.80	
	Min, Max	1.0, 7.0		1.0, 7.0		3.2, 6.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 1 - Reward****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	46	46	27	27	7	7
	Missing, n(%)	1 (2.1)	1 (2.1)	5 (15.6)	5 (15.6)	2 (22.2)	2 (22.2)
	Mean (SD)	4.53 (1.529)	-0.84 (46.144)	4.63 (1.583)	5.46 (36.306)	2.59 (1.505)	-42.06 (44.485)
	95% CI of Mean	4.07, 4.99	-14.55, 12.87	4.00, 5.26	-8.91, 19.82	1.20, 3.99	-83.20, -0.91
	Median	4.40	-10.29	4.80	0.00	2.60	-56.67
	Q25, Q75	3.80, 5.60	-23.53, 9.38	3.40, 6.00	-15.63, 21.43	1.20, 2.75	-62.50, -40.22
	Min, Max	1.0, 7.0	-80.0, 200.0	1.6, 7.0	-57.1, 107.7	1.0, 5.6	-78.3, 55.6

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Mean (SD)	3.57 (1.848)		3.57 (1.852)		3.26 (1.341)	
	95% CI of Mean	3.14, 4.00		2.93, 4.21		2.69, 3.83	
	Median	3.40		3.00		3.30	
	Q25, Q75	2.00, 5.00		2.20, 5.40		2.40, 4.30	
	Min, Max	1.0, 7.0		1.0, 7.0		1.0, 5.6	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	75	75	33	33	24	24
	Missing, n(%)	0	0	2 (5.7)	2 (5.7)	0	0
	Mean (SD)	3.35 (1.824)	5.43 (67.122)	3.70 (1.745)	19.23 (69.650)	4.48 (1.588)	65.32 (109.447)
	95% CI of Mean	2.92, 3.77	-10.02, 20.87	3.07, 4.32	-5.47, 43.93	3.80, 5.15	19.10, 111.54
	Median	3.00	0.00	3.40	0.00	4.50	32.50
	Q25, Q75	1.80, 4.80	-16.67, 20.00	2.40, 5.20	-11.11, 20.69	2.90, 5.60	6.25, 93.33
	Min, Max	1.0, 7.0	-82.8, 480.0	1.0, 7.0	-61.5, 240.0	1.6, 7.0	-41.7, 480.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	3.31 (1.863)	6.73 (81.716)	3.41 (1.742)	14.93 (85.069)	3.95 (1.767)	39.21 (93.226)
	95% CI of Mean	2.87, 3.74	-12.07, 25.54	2.79, 4.02	-14.76, 44.61	3.20, 4.70	-0.17, 78.58
	Median	3.20	0.00	3.30	0.00	3.90	21.32
	Q25, Q75	1.80, 4.40	-28.00, 17.65	1.80, 4.80	-23.33, 30.77	2.40, 5.60	-6.46, 56.87
	Min, Max	1.0, 7.0	-84.8, 600.0	1.0, 7.0	-70.0, 360.0	1.4, 7.0	-66.7, 420.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	75	75	34	34	23	23
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Mean (SD)	3.25 (1.631)	5.23 (72.243)	3.46 (1.708)	6.19 (47.391)	3.26 (1.708)	17.87 (77.593)
	95% CI of Mean	2.87, 3.63	-11.39, 21.86	2.86, 4.06	-10.35, 22.73	2.52, 4.00	-15.68, 51.43
	Median	3.20	-5.00	3.50	0.00	3.00	0.00
	Q25, Q75	1.80, 4.40	-26.09, 10.00	2.00, 5.20	-22.86, 20.69	1.80, 5.00	-18.75, 44.44
	Min, Max	1.0, 7.0	-84.8, 500.0	1.0, 7.0	-61.5, 180.0	1.0, 7.0	-79.2, 280.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	3.26 (1.825)	4.82 (83.002)	3.61 (1.963)	26.79 (116.505)	2.97 (1.718)	8.61 (83.103)
	95% CI of Mean	2.84, 3.69	-14.29, 23.92	2.92, 4.30	-13.86, 67.45	2.24, 3.70	-26.49, 43.71
	Median	3.00	0.00	4.00	2.50	2.50	-7.18
	Q25, Q75	1.80, 4.40	-30.00, 15.38	1.80, 5.60	-27.27, 23.08	1.50, 4.00	-36.07, 20.83
	Min, Max	1.0, 7.0	-84.8, 600.0	1.0, 7.0	-83.3, 500.0	1.0, 7.0	-79.2, 300.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	3.18 (1.706)	-0.17 (66.968)	3.48 (1.874)	9.84 (57.928)	3.12 (1.811)	7.23 (75.940)
	95% CI of Mean	2.78, 3.58	-15.58, 15.25	2.82, 4.14	-10.38, 30.06	2.35, 3.89	-24.85, 39.30
	Median	3.20	-10.71	3.00	0.00	3.00	0.00
	Q25, Q75	1.80, 4.40	-25.71, 8.70	2.00, 5.20	-18.18, 20.69	1.30, 4.60	-20.87, 23.61
	Min, Max	1.0, 7.0	-75.0, 480.0	1.0, 7.0	-83.3, 200.0	1.0, 7.0	-79.2, 300.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34		13	
	Mean (SD)	4.04 (1.722)		3.48 (1.845)		3.54 (1.210)	
	95% CI of Mean	3.48, 4.59		2.83, 4.12		2.80, 4.27	
	Median	4.20		3.00		4.00	
	Q25, Q75	2.50, 5.60		2.00, 5.20		3.00, 4.60	
	Min, Max	1.0, 7.0		1.0, 7.0		1.0, 5.2	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	39	39	32	32	13	13
	Missing, n(%)	1 (2.5)	1 (2.5)	2 (5.9)	2 (5.9)	0	0
	Mean (SD)	3.28 (1.483)	-11.86 (44.646)	3.64 (1.873)	14.68 (51.514)	1.80 (0.726)	-39.83 (41.430)
	95% CI of Mean	2.79, 3.76	-26.34, 2.61	2.96, 4.32	-3.89, 33.26	1.36, 2.24	-64.87, -14.79
	Median	3.20	-17.86	3.70	0.00	1.60	-52.17
	Q25, Q75	2.00, 4.40	-39.29, 0.00	1.80, 5.20	-15.38, 32.05	1.20, 2.20	-66.67, -30.77
	Min, Max	1.0, 7.0	-79.3, 180.0	1.0, 7.0	-65.0, 160.0	1.0, 3.6	-73.9, 80.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35		12	
	Mean (SD)	3.92 (1.748)		3.55 (1.867)		3.47 (1.143)	
	95% CI of Mean	3.35, 4.49		2.90, 4.19		2.74, 4.20	
	Median	4.00		3.00		3.60	
	Q25, Q75	2.20, 5.60		2.00, 5.40		2.80, 4.30	
	Min, Max	1.0, 7.0		1.0, 7.0		1.4, 5.2	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	32	32	11	11
	Missing, n(%)	0	0	3 (8.6)	3 (8.6)	1 (8.3)	1 (8.3)
	Mean (SD)	3.17 (1.434)	-3.99 (63.420)	3.81 (1.626)	17.96 (68.183)	1.80 (0.840)	-43.36 (31.777)
	95% CI of Mean	2.70, 3.64	-24.55, 16.58	3.22, 4.40	-6.63, 42.54	1.23, 2.37	-64.71, -22.00
	Median	3.20	-11.76	3.80	0.00	1.80	-44.44
	Q25, Q75	2.20, 3.80	-42.42, 0.00	2.50, 5.10	-11.35, 28.53	1.00, 2.60	-66.67, -37.50
	Min, Max	1.0, 7.0	-82.9, 287.5	1.2, 7.0	-70.0, 300.0	1.0, 3.2	-75.0, 42.9

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	3.82 (1.694)		3.62 (1.822)		3.18 (1.129)	
	95% CI of Mean	3.31, 4.32		2.96, 4.28		2.31, 4.05	
	Median	4.00		3.40		3.20	
	Q25, Q75	2.20, 5.40		2.20, 5.30		2.60, 4.00	
	Min, Max	1.0, 7.0		1.0, 7.0		1.4, 4.6	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Factor 2 - Relief****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	46	46	27	27	7	7
	Missing, n(%)	1 (2.1)	1 (2.1)	5 (15.6)	5 (15.6)	2 (22.2)	2 (22.2)
	Mean (SD)	3.14 (1.450)	-8.68 (40.301)	3.23 (1.648)	-6.37 (30.538)	1.59 (0.641)	-35.48 (54.248)
	95% CI of Mean	2.71, 3.58	-20.66, 3.29	2.57, 3.89	-18.45, 5.72	1.00, 2.19	-85.65, 14.70
	Median	2.90	-14.55	3.40	-9.09	1.60	-52.17
	Q25, Q75	2.00, 4.20	-34.48, 12.50	1.80, 4.20	-30.77, 13.33	1.00, 2.20	-61.54, -44.44
	Min, Max	1.0, 7.0	-75.0, 116.7	1.0, 6.0	-54.5, 75.0	1.0, 2.6	-70.6, 85.7

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Mean (SD)	4.19 (1.694)		4.17 (1.859)		3.99 (1.358)	
	95% CI of Mean	3.79, 4.58		3.53, 4.82		3.41, 4.57	
	Median	4.10		4.50		3.90	
	Q25, Q75	2.80, 5.50		2.70, 5.80		3.10, 5.20	
	Min, Max	1.0, 7.0		1.0, 7.0		1.2, 6.1	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	75	75	33	33	24	24
	Missing, n(%)	0	0	2 (5.7)	2 (5.7)	0	0
	Mean (SD)	3.93 (1.728)	4.34 (61.276)	4.13 (1.769)	21.32 (92.757)	5.16 (1.307)	52.64 (100.127)
	95% CI of Mean	3.53, 4.33	-9.76, 18.45	3.50, 4.76	-11.57, 54.22	4.61, 5.72	10.36, 94.93
	Median	3.90	-2.94	4.00	0.00	5.30	22.51
	Q25, Q75	2.60, 5.20	-23.88, 14.81	2.90, 5.70	-14.89, 9.62	4.40, 6.15	2.88, 58.79
	Min, Max	1.0, 7.0	-84.4, 392.3	1.0, 7.0	-77.8, 390.0	2.5, 7.0	-40.4, 433.3

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	3.86 (1.740)	5.64 (72.669)	3.94 (1.802)	17.00 (87.891)	4.66 (1.566)	38.11 (93.689)
	95% CI of Mean	3.45, 4.26	-11.08, 22.37	3.30, 4.57	-13.68, 47.67	4.00, 5.33	-1.45, 77.68
	Median	3.70	-4.17	4.00	0.00	5.15	12.59
	Q25, Q75	2.50, 5.00	-27.78, 12.00	2.40, 5.70	-28.89, 40.54	3.35, 5.85	-9.34, 66.77
	Min, Max	1.0, 7.0	-85.3, 438.5	1.0, 7.0	-78.3, 360.0	1.7, 7.0	-57.7, 383.3

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	75	75	34	34	23	23
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Mean (SD)	3.85 (1.524)	5.35 (68.608)	3.86 (1.803)	5.48 (63.358)	3.97 (1.621)	20.46 (78.436)
	95% CI of Mean	3.50, 4.21	-10.44, 21.14	3.23, 4.50	-16.63, 27.59	3.26, 4.67	-13.47, 54.38
	Median	3.90	-6.78	4.00	-2.81	4.10	1.96
	Q25, Q75	2.80, 5.00	-27.78, 12.50	2.00, 5.60	-16.67, 12.82	3.20, 5.20	-11.11, 64.00
	Min, Max	1.0, 7.0	-85.3, 400.0	1.0, 7.0	-77.8, 310.0	1.0, 7.0	-82.8, 258.3

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	3.83 (1.705)	3.46 (72.544)	4.11 (1.932)	26.84 (112.948)	3.78 (1.642)	12.24 (80.876)
	95% CI of Mean	3.43, 4.23	-13.24, 20.15	3.43, 4.79	-12.58, 66.25	3.08, 4.47	-21.92, 46.40
	Median	3.60	-5.41	4.30	1.22	3.50	-0.82
	Q25, Q75	2.60, 5.00	-21.74, 10.34	2.20, 6.00	-17.14, 35.71	2.85, 5.10	-42.21, 34.48
	Min, Max	1.0, 7.0	-85.3, 438.5	1.0, 7.0	-84.6, 450.0	1.0, 7.0	-73.1, 300.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	3.78 (1.621)	-0.84 (58.960)	3.86 (1.846)	9.25 (69.189)	3.95 (1.843)	15.60 (87.940)
	95% CI of Mean	3.41, 4.16	-14.41, 12.73	3.21, 4.51	-14.89, 33.40	3.17, 4.74	-21.54, 52.74
	Median	3.80	-10.71	3.65	0.00	3.90	0.82
	Q25, Q75	2.50, 5.10	-26.47, 11.11	2.50, 5.60	-10.00, 15.38	2.95, 5.55	-12.71, 33.20
	Min, Max	1.0, 7.0	-75.0, 392.3	1.0, 7.0	-84.6, 310.0	1.0, 7.0	-80.8, 358.3

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34		13	
	Mean (SD)	4.59 (1.609)		4.04 (1.866)		4.47 (1.019)	
	95% CI of Mean	4.07, 5.11		3.39, 4.70		3.85, 5.09	
	Median	4.75		4.10		4.00	
	Q25, Q75	3.75, 6.10		2.30, 5.70		3.70, 5.20	
	Min, Max	1.0, 7.0		1.0, 7.0		2.9, 6.1	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	39	39	32	32	13	13
	Missing, n(%)	1 (2.5)	1 (2.5)	2 (5.9)	2 (5.9)	0	0
	Mean (SD)	4.01 (1.253)	-7.17 (33.206)	4.07 (1.753)	14.96 (61.332)	2.49 (1.090)	-41.37 (28.755)
	95% CI of Mean	3.60, 4.42	-17.94, 3.60	3.44, 4.71	-7.16, 37.08	1.83, 3.16	-58.75, -23.99
	Median	4.00	-12.50	3.95	-1.22	2.80	-42.31
	Q25, Q75	3.10, 4.90	-29.41, 5.77	2.25, 5.80	-21.70, 30.56	1.50, 3.10	-70.00, -20.51
	Min, Max	1.6, 7.0	-75.0, 72.2	1.4, 7.0	-63.0, 210.0	1.0, 4.4	-77.6, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35		12	
	Mean (SD)	4.53 (1.549)		4.11 (1.885)		4.33 (1.087)	
	95% CI of Mean	4.02, 5.04		3.46, 4.76		3.64, 5.03	
	Median	4.60		4.10		4.25	
	Q25, Q75	3.60, 6.10		2.30, 5.80		3.65, 5.15	
	Min, Max	1.0, 7.0		1.0, 7.0		2.5, 6.1	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	32	32	11	11
	Missing, n(%)	0	0	3 (8.6)	3 (8.6)	1 (8.3)	1 (8.3)
	Mean (SD)	4.07 (1.222)	0.47 (47.317)	4.48 (1.504)	26.01 (80.218)	2.41 (1.175)	-40.66 (38.657)
	95% CI of Mean	3.67, 4.48	-14.87, 15.82	3.93, 5.03	-2.92, 54.93	1.62, 3.20	-66.64, -14.69
	Median	3.90	-5.00	4.30	0.00	2.40	-38.46
	Q25, Q75	3.40, 4.80	-25.00, 12.50	3.70, 5.80	-11.11, 45.19	1.10, 3.20	-71.43, -36.07
	Min, Max	1.0, 7.0	-73.0, 180.0	1.3, 7.0	-71.7, 280.0	1.0, 4.0	-78.0, 60.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	4.40 (1.536)		4.17 (1.853)		3.99 (0.963)	
	95% CI of Mean	3.95, 4.86		3.50, 4.84		3.24, 4.73	
	Median	4.20		4.30		3.90	
	Q25, Q75	3.60, 6.10		2.80, 5.75		3.50, 5.00	
	Min, Max	1.0, 7.0		1.0, 7.0		2.5, 5.2	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.1 Descriptive Statistics of QSU-brief Factors and Total Scores - PP Set****Parameter: Total Score****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	46	46	27	27	7	7
	Missing, n(%)	1 (2.1)	1 (2.1)	5 (15.6)	5 (15.6)	2 (22.2)	2 (22.2)
	Mean (SD)	3.84 (1.343)	-5.41 (39.046)	3.93 (1.499)	0.32 (30.059)	2.09 (1.030)	-40.13 (46.974)
	95% CI of Mean	3.43, 4.24	-17.01, 6.19	3.33, 4.53	-11.58, 12.21	1.14, 3.05	-83.58, 3.32
	Median	3.80	-10.46	3.90	-3.70	2.10	-54.90
	Q25, Q75	2.70, 4.60	-26.23, 8.11	2.60, 4.90	-20.41, 10.00	1.10, 2.30	-62.07, -42.31
	Min, Max	1.1, 7.0	-73.8, 150.0	1.4, 6.3	-56.5, 68.2	1.0, 4.1	-75.0, 64.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 1 - Reward**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41		39	
	Mean (SD)	4.76 (1.720)		4.64 (1.976)		4.69 (1.672)	
	95% CI of Mean	4.37, 5.14		4.02, 5.27		4.15, 5.24	
	Median	4.80		5.00		4.60	
	Q25, Q75	3.60, 6.40		3.20, 6.20		3.40, 6.00	
	Min, Max	1.0, 7.0		1.0, 7.0		1.4, 7.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 1 - Reward**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	79	79	39	39	35	35
	Missing, n(%)	1 (1.3)	1 (1.3)	2 (4.9)	2 (4.9)	4 (10.3)	4 (10.3)
	Mean (SD)	4.52 (1.853)	5.93 (60.252)	4.32 (1.933)	20.94 (119.670)	5.63 (1.353)	42.38 (85.734)
	95% CI of Mean	4.10, 4.94	-7.57, 19.43	3.69, 4.95	-17.85, 59.74	5.16, 6.10	12.92, 71.83
	Median	4.60	0.00	4.20	0.00	5.80	20.69
	Q25, Q75	3.00, 6.20	-20.00, 16.67	2.60, 6.00	-20.00, 16.67	5.20, 6.80	-3.23, 55.00
	Min, Max	1.0, 7.0	-85.7, 337.5	1.0, 7.0	-84.4, 580.0	1.8, 7.0	-50.0, 400.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 1 - Reward**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	79	79	40	40	34	34
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
	Mean (SD)	4.35 (1.783)	7.04 (79.179)	4.37 (1.992)	22.86 (105.376)	5.15 (1.804)	32.84 (86.151)
	95% CI of Mean	3.95, 4.75	-10.70, 24.78	3.73, 5.01	-10.84, 56.57	4.52, 5.79	2.77, 62.90
	Median	4.20	-3.45	4.50	0.00	6.10	1.67
	Q25, Q75	3.20, 5.80	-27.59, 11.54	2.80, 6.10	-34.85, 49.39	3.40, 6.60	-16.13, 61.90
	Min, Max	1.0, 7.0	-85.7, 380.0	1.0, 7.0	-85.7, 460.0	2.0, 7.0	-64.3, 357.1

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 1 - Reward**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	79	79	40	40	33	33
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	6 (15.4)	6 (15.4)
	Mean (SD)	4.46 (1.654)	8.36 (74.195)	4.12 (2.024)	6.67 (86.057)	4.54 (1.964)	18.51 (76.281)
	95% CI of Mean	4.09, 4.84	-8.26, 24.98	3.46, 4.77	-20.86, 34.19	3.84, 5.24	-8.55, 45.56
	Median	4.40	-5.00	4.00	0.00	5.00	0.00
	Q25, Q75	3.20, 6.00	-23.81, 13.33	2.10, 6.00	-19.52, 14.71	2.80, 6.00	-21.43, 40.00
	Min, Max	1.0, 7.0	-85.7, 400.0	1.0, 7.0	-84.4, 480.0	1.0, 7.0	-85.7, 242.9

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 1 - Reward**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	79	79	40	40	34	34
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
	Mean (SD)	4.37 (1.786)	3.60 (70.420)	4.37 (2.057)	25.88 (129.438)	4.45 (1.924)	13.65 (75.066)
	95% CI of Mean	3.97, 4.78	-12.18, 19.38	3.71, 5.03	-15.52, 67.28	3.77, 5.12	-12.55, 39.84
	Median	4.20	-4.35	4.70	0.00	4.40	0.00
	Q25, Q75	3.00, 6.00	-22.22, 5.26	2.60, 6.00	-30.30, 30.15	3.00, 6.00	-33.33, 40.00
	Min, Max	1.0, 7.0	-85.7, 400.0	1.0, 7.0	-85.7, 600.0	1.0, 7.0	-78.3, 300.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 1 - Reward**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	40	40	34	34
	Missing, n(%)	2 (2.5)	2 (2.5)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
	Mean (SD)	4.41 (1.799)	-0.03 (56.429)	3.99 (1.978)	6.22 (84.118)	4.58 (2.203)	16.29 (87.588)
	95% CI of Mean	4.00, 4.82	-12.76, 12.69	3.35, 4.63	-20.68, 33.13	3.81, 5.36	-14.27, 46.86
	Median	4.20	-9.09	4.00	0.00	4.90	0.00
	Q25, Q75	3.20, 6.00	-28.57, 18.18	2.20, 5.80	-34.67, 9.19	2.60, 7.00	-26.67, 33.33
	Min, Max	1.0, 7.0	-78.3, 337.5	1.0, 7.0	-85.7, 420.0	1.0, 7.0	-82.1, 400.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 1 - Reward**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	76	76	38	38	33	33
	Missing, n(%)	4 (5.0)	4 (5.0)	3 (7.3)	3 (7.3)	6 (15.4)	6 (15.4)
	Mean (SD)	4.73 (1.466)	15.39 (72.029)	4.30 (1.830)	12.00 (72.607)	3.65 (1.645)	-5.93 (61.027)
	95% CI of Mean	4.39, 5.07	-1.07, 31.86	3.69, 4.91	-11.87, 35.87	3.07, 4.24	-27.57, 15.72
	Median	4.70	0.00	4.00	-4.46	3.80	0.00
	Q25, Q75	4.00, 5.80	-22.22, 20.73	2.80, 6.00	-37.50, 25.00	2.60, 4.60	-53.57, 17.65
	Min, Max	1.2, 7.0	-72.0, 366.7	1.0, 7.0	-81.5, 280.0	1.0, 7.0	-80.0, 214.3

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 1 - Reward**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	74	74	36	36	31	31
	Missing, n(%)	6 (7.5)	6 (7.5)	5 (12.2)	5 (12.2)	8 (20.5)	8 (20.5)
	Mean (SD)	4.82 (1.447)	14.25 (64.680)	5.06 (1.569)	30.07 (99.601)	3.41 (1.728)	-15.40 (53.961)
	95% CI of Mean	4.48, 5.16	-0.74, 29.24	4.53, 5.60	-3.63, 63.78	2.77, 4.04	-35.19, 4.40
	Median	4.80	0.00	5.50	1.52	3.00	-34.29
	Q25, Q75	3.80, 6.00	-20.00, 26.92	4.00, 6.50	-13.12, 35.42	2.20, 5.00	-60.00, 25.00
	Min, Max	1.0, 7.0	-70.6, 312.5	1.4, 7.0	-80.0, 480.0	1.0, 7.0	-80.0, 115.4

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 1 - Reward**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	71	71	31	31	29	29
	Missing, n(%)	9 (11.3)	9 (11.3)	10 (24.4)	10 (24.4)	10 (25.6)	10 (25.6)
	Mean (SD)	4.60 (1.605)	7.73 (64.532)	4.40 (1.646)	0.47 (38.472)	3.59 (1.803)	-2.07 (84.825)
	95% CI of Mean	4.22, 4.99	-7.55, 23.01	3.79, 5.01	-13.64, 14.59	2.90, 4.28	-34.35, 30.20
	Median	4.60	-8.33	4.00	-3.33	3.40	-34.29
	Q25, Q75	3.80, 5.80	-25.00, 27.78	3.40, 5.80	-20.00, 17.65	2.00, 5.00	-57.14, 20.69
	Min, Max	1.0, 7.0	-80.0, 337.5	1.0, 7.0	-81.5, 107.7	1.0, 7.0	-78.3, 285.7

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 2 - Relief**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41		39	
	Mean (SD)	3.50 (1.815)		3.50 (1.764)		3.32 (1.585)	
	95% CI of Mean	3.09, 3.91		2.94, 4.06		2.80, 3.84	
	Median	3.20		3.00		3.20	
	Q25, Q75	2.00, 4.70		2.20, 5.20		1.80, 4.40	
	Min, Max	1.0, 7.0		1.0, 7.0		1.0, 7.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 2 - Relief**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	79	79	39	39	35	35
	Missing, n(%)	1 (1.3)	1 (1.3)	2 (4.9)	2 (4.9)	4 (10.3)	4 (10.3)
	Mean (SD)	3.35 (1.836)	7.40 (68.436)	3.48 (1.723)	13.34 (66.862)	4.30 (1.675)	61.08 (101.742)
	95% CI of Mean	2.94, 3.77	-7.94, 22.73	2.91, 4.04	-8.34, 35.02	3.72, 4.88	26.12, 96.03
	Median	3.00	0.00	3.20	0.00	4.40	36.36
	Q25, Q75	1.80, 4.80	-16.67, 20.00	2.00, 5.20	-15.38, 20.69	2.80, 5.60	0.00, 86.67
	Min, Max	1.0, 7.0	-82.8, 480.0	1.0, 7.0	-76.2, 240.0	1.0, 7.0	-50.0, 480.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 2 - Relief**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	79	79	40	40	34	34
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
	Mean (SD)	3.25 (1.835)	6.17 (79.735)	3.28 (1.681)	11.57 (81.008)	3.72 (1.795)	37.09 (87.761)
	95% CI of Mean	2.84, 3.67	-11.70, 24.03	2.73, 3.82	-14.34, 37.48	3.09, 4.35	6.46, 67.71
	Median	3.00	0.00	3.20	0.00	3.70	25.83
	Q25, Q75	1.80, 4.40	-24.14, 17.65	1.80, 4.60	-27.88, 26.92	2.00, 5.40	-6.67, 52.63
	Min, Max	1.0, 7.0	-84.8, 600.0	1.0, 7.0	-76.2, 360.0	1.2, 7.0	-66.7, 420.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 2 - Relief**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	79	79	40	40	33	33
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	6 (15.4)	6 (15.4)
	Mean (SD)	3.24 (1.605)	6.34 (70.775)	3.25 (1.673)	2.04 (47.160)	3.11 (1.638)	16.98 (72.898)
	95% CI of Mean	2.88, 3.60	-9.52, 22.20	2.71, 3.79	-13.05, 17.13	2.52, 3.69	-8.88, 42.83
	Median	3.20	-4.35	2.90	0.00	3.00	6.67
	Q25, Q75	1.80, 4.40	-25.00, 15.00	1.90, 4.70	-22.97, 20.34	1.80, 4.00	-18.75, 36.36
	Min, Max	1.0, 7.0	-84.8, 500.0	1.0, 7.0	-76.2, 180.0	1.0, 7.0	-79.2, 280.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 2 - Relief**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	79	79	40	40	34	34
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
	Mean (SD)	3.24 (1.792)	5.39 (81.097)	3.41 (1.936)	20.51 (109.961)	2.83 (1.641)	7.55 (75.655)
	95% CI of Mean	2.83, 3.64	-12.78, 23.56	2.79, 4.03	-14.66, 55.68	2.25, 3.41	-18.85, 33.95
	Median	3.00	0.00	3.10	-1.79	2.50	-7.42
	Q25, Q75	1.80, 4.40	-28.57, 16.67	1.60, 5.20	-28.64, 22.65	1.40, 4.00	-35.29, 25.00
	Min, Max	1.0, 7.0	-84.8, 600.0	1.0, 7.0	-83.3, 500.0	1.0, 7.0	-79.2, 300.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 2 - Relief**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	40	40	34	34
	Missing, n(%)	2 (2.5)	2 (2.5)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
	Mean (SD)	3.20 (1.685)	1.44 (66.538)	3.29 (1.839)	5.76 (57.876)	2.96 (1.716)	7.99 (71.368)
	95% CI of Mean	2.81, 3.58	-13.57, 16.44	2.70, 3.88	-12.75, 24.28	2.36, 3.57	-16.92, 32.90
	Median	3.10	-10.17	3.00	0.00	2.90	0.00
	Q25, Q75	1.80, 4.40	-25.00, 8.70	1.80, 4.40	-29.06, 20.69	1.20, 4.00	-22.73, 22.73
	Min, Max	1.0, 7.0	-75.0, 480.0	1.0, 7.0	-83.3, 200.0	1.0, 7.0	-79.2, 300.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 2 - Relief**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	76	76	38	38	33	33
	Missing, n(%)	4 (5.0)	4 (5.0)	3 (7.3)	3 (7.3)	6 (15.4)	6 (15.4)
	Mean (SD)	3.21 (1.546)	6.06 (64.656)	3.44 (1.827)	7.92 (52.054)	2.07 (0.875)	-19.81 (44.454)
	95% CI of Mean	2.85, 3.56	-8.72, 20.84	2.83, 4.04	-9.20, 25.03	1.76, 2.39	-35.57, -4.04
	Median	3.20	-8.19	3.20	0.00	2.00	-20.00
	Q25, Q75	2.00, 4.30	-35.32, 25.83	1.80, 5.00	-18.18, 30.77	1.40, 2.40	-52.17, 0.00
	Min, Max	1.0, 7.0	-79.3, 300.0	1.0, 7.0	-76.2, 160.0	1.0, 4.0	-73.9, 120.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 2 - Relief**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	74	74	36	36	31	31
	Missing, n(%)	6 (7.5)	6 (7.5)	5 (12.2)	5 (12.2)	8 (20.5)	8 (20.5)
	Mean (SD)	3.01 (1.505)	-1.04 (67.361)	3.70 (1.582)	13.92 (65.739)	2.10 (1.248)	-23.28 (42.176)
	95% CI of Mean	2.65, 3.36	-16.65, 14.57	3.16, 4.24	-8.33, 36.17	1.64, 2.57	-38.76, -7.81
	Median	2.90	-11.05	3.60	-1.43	2.00	-34.78
	Q25, Q75	1.60, 3.80	-36.36, 12.50	2.40, 4.90	-18.68, 20.34	1.00, 2.60	-53.85, 0.00
	Min, Max	1.0, 7.0	-82.9, 360.0	1.2, 7.0	-70.0, 300.0	1.0, 6.0	-75.0, 100.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Factor 2 - Relief**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	71	71	31	31	29	29
	Missing, n(%)	9 (11.3)	9 (11.3)	10 (24.4)	10 (24.4)	10 (25.6)	10 (25.6)
	Mean (SD)	3.08 (1.566)	-3.99 (51.720)	3.17 (1.614)	-8.00 (32.056)	2.15 (1.405)	-20.10 (47.795)
	95% CI of Mean	2.71, 3.46	-16.23, 8.26	2.57, 3.76	-19.77, 3.76	1.61, 2.69	-38.28, -1.91
	Median	2.80	-14.29	3.40	-15.00	1.75	-30.00
	Q25, Q75	1.80, 4.20	-37.50, 13.33	1.80, 4.20	-30.77, 13.33	1.00, 3.00	-53.33, 0.00
	Min, Max	1.0, 7.0	-75.0, 260.0	1.0, 6.0	-76.2, 75.0	1.0, 7.0	-79.2, 122.2

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Total Score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41		39	
	Mean (SD)	4.13 (1.672)		4.07 (1.787)		4.01 (1.513)	
	95% CI of Mean	3.75, 4.50		3.50, 4.64		3.51, 4.50	
	Median	4.00		4.10		3.90	
	Q25, Q75	2.80, 5.30		2.70, 5.60		2.80, 5.20	
	Min, Max	1.0, 7.0		1.0, 7.0		1.2, 7.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Total Score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	79	79	39	39	35	35
	Missing, n(%)	1 (1.3)	1 (1.3)	2 (4.9)	2 (4.9)	4 (10.3)	4 (10.3)
	Mean (SD)	3.94 (1.729)	5.27 (60.549)	3.90 (1.762)	15.22 (87.196)	4.97 (1.415)	47.72 (89.572)
	95% CI of Mean	3.54, 4.33	-8.29, 18.84	3.32, 4.48	-13.05, 43.49	4.47, 5.46	16.94, 78.49
	Median	3.90	-2.50	4.00	-1.72	5.10	25.00
	Q25, Q75	2.60, 5.20	-22.73, 15.15	2.10, 5.70	-16.22, 9.62	3.80, 6.10	0.00, 64.52
	Min, Max	1.0, 7.0	-84.4, 392.3	1.0, 7.0	-77.8, 390.0	1.4, 7.0	-50.0, 433.3

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Total Score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	79	79	40	40	34	34
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
	Mean (SD)	3.80 (1.721)	4.69 (71.029)	3.82 (1.765)	15.38 (84.442)	4.44 (1.635)	34.01 (84.724)
	95% CI of Mean	3.41, 4.19	-11.22, 20.60	3.25, 4.39	-11.63, 42.39	3.86, 5.01	4.44, 63.57
	Median	3.70	-4.41	4.00	0.00	4.90	14.54
	Q25, Q75	2.50, 4.90	-27.78, 12.00	2.35, 5.30	-32.70, 42.68	2.90, 5.80	-8.33, 58.06
	Min, Max	1.0, 7.0	-85.3, 438.5	1.0, 7.0	-79.2, 360.0	1.7, 7.0	-57.7, 383.3

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Total Score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	79	79	40	40	33	33
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	6 (15.4)	6 (15.4)
	Mean (SD)	3.85 (1.506)	6.18 (67.108)	3.68 (1.764)	2.85 (60.829)	3.82 (1.635)	17.61 (72.633)
	95% CI of Mean	3.51, 4.19	-8.86, 21.22	3.11, 4.25	-16.61, 22.31	3.24, 4.41	-8.15, 43.37
	Median	3.90	-6.06	3.85	-2.10	4.10	0.00
	Q25, Q75	2.80, 5.00	-22.92, 14.81	2.10, 5.30	-17.91, 14.10	2.40, 5.10	-13.46, 34.04
	Min, Max	1.0, 7.0	-85.3, 400.0	1.0, 7.0	-79.2, 310.0	1.0, 7.0	-82.8, 258.3

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Total Score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	79	79	40	40	34	34
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
	Mean (SD)	3.81 (1.690)	3.40 (70.761)	3.89 (1.907)	20.91 (106.339)	3.64 (1.627)	10.54 (72.672)
	95% CI of Mean	3.42, 4.19	-12.46, 19.25	3.28, 4.50	-13.10, 54.92	3.07, 4.21	-14.83, 35.90
	Median	3.50	-5.41	3.55	0.00	3.50	-0.82
	Q25, Q75	2.60, 5.00	-20.00, 10.71	2.25, 5.65	-27.32, 32.14	2.30, 4.80	-32.69, 34.04
	Min, Max	1.0, 7.0	-85.3, 438.5	1.0, 7.0	-84.6, 450.0	1.0, 7.0	-75.0, 300.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Total Score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	78	78	40	40	34	34
	Missing, n(%)	2 (2.5)	2 (2.5)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
	Mean (SD)	3.80 (1.612)	-0.32 (57.938)	3.64 (1.831)	4.55 (67.033)	3.77 (1.795)	13.17 (78.764)
	95% CI of Mean	3.44, 4.17	-13.39, 12.75	3.05, 4.23	-16.90, 25.99	3.14, 4.40	-14.32, 40.66
	Median	3.80	-8.83	3.50	0.00	3.70	1.80
	Q25, Q75	2.50, 5.10	-25.93, 12.50	2.05, 4.80	-34.45, 15.59	2.10, 5.50	-20.83, 31.91
	Min, Max	1.0, 7.0	-75.0, 392.3	1.0, 7.0	-84.6, 310.0	1.0, 7.0	-80.8, 358.3

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Total Score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	76	76	38	38	33	33
	Missing, n(%)	4 (5.0)	4 (5.0)	3 (7.3)	3 (7.3)	6 (15.4)	6 (15.4)
	Mean (SD)	3.97 (1.337)	9.54 (61.284)	3.87 (1.765)	9.18 (60.869)	2.86 (1.157)	-12.79 (52.015)
	95% CI of Mean	3.66, 4.28	-4.47, 23.55	3.28, 4.45	-10.83, 29.19	2.45, 3.28	-31.24, 5.65
	Median	4.00	-2.23	3.60	-1.22	3.00	-11.11
	Q25, Q75	3.20, 4.70	-24.89, 24.03	2.20, 5.50	-32.43, 27.78	2.00, 3.50	-58.33, 7.14
	Min, Max	1.1, 7.0	-75.0, 284.6	1.0, 7.0	-79.2, 210.0	1.0, 5.4	-77.6, 175.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Total Score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	74	74	36	36	31	31
	Missing, n(%)	6 (7.5)	6 (7.5)	5 (12.2)	5 (12.2)	8 (20.5)	8 (20.5)
	Mean (SD)	3.91 (1.307)	6.57 (58.951)	4.38 (1.459)	21.93 (76.640)	2.75 (1.366)	-18.95 (47.958)
	95% CI of Mean	3.60, 4.22	-7.09, 20.24	3.88, 4.88	-4.01, 47.87	2.25, 3.26	-36.55, -1.36
	Median	3.85	-4.43	3.95	0.00	2.30	-36.07
	Q25, Q75	3.00, 4.60	-26.67, 21.74	3.65, 5.75	-16.55, 29.23	1.90, 3.80	-58.33, 10.53
	Min, Max	1.0, 7.0	-73.0, 330.8	1.3, 7.0	-71.7, 280.0	1.0, 6.3	-78.0, 105.3

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.52.2 Descriptive Statistics of QSU-brief Factors and Total Scores - FAS Set****Parameter: Total Score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	71	71	31	31	29	29
	Missing, n(%)	9 (11.3)	9 (11.3)	10 (24.4)	10 (24.4)	10 (25.6)	10 (25.6)
	Mean (SD)	3.84 (1.449)	1.66 (55.371)	3.78 (1.510)	-3.21 (32.415)	2.87 (1.506)	-10.56 (65.314)
	95% CI of Mean	3.50, 4.19	-11.45, 14.77	3.23, 4.34	-15.11, 8.68	2.29, 3.45	-35.41, 14.29
	Median	3.80	-8.51	3.70	-5.56	2.30	-34.48
	Q25, Q75	2.80, 4.90	-30.51, 17.86	2.50, 4.70	-21.43, 10.00	1.80, 3.80	-58.00, 10.64
	Min, Max	1.0, 7.0	-73.8, 307.7	1.0, 6.3	-79.2, 68.2	1.0, 7.0	-75.0, 168.4

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Factor 1 - Reward						
Day 1	n	75	33	24		
	LS Mean	4.51	4.62	5.88	-0.10	-1.37
	95% CI	4.13, 4.90	4.05, 5.18	5.22, 6.55	-0.78, 0.58	-2.13, -0.61
Day 2	n	75	34	24		
	LS Mean	4.42	4.49	5.40	-0.07	-0.98
	95% CI	3.99, 4.84	3.87, 5.11	4.67, 6.13	-0.81, 0.67	-1.82, -0.15
Day 3	n	75	34	23		
	LS Mean	4.46	4.28	4.75	0.18	-0.29
	95% CI	4.05, 4.86	3.69, 4.87	4.03, 5.47	-0.53, 0.89	-1.11, 0.52
Day 4	n	75	34	24		
	LS Mean	4.43	4.65	4.65	-0.22	-0.22
	95% CI	4.01, 4.85	4.04, 5.27	3.92, 5.38	-0.96, 0.51	-1.05, 0.62

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Factor 1 - Reward (cont...)						
Day 5	n	75	34	24		
	LS Mean	4.38	4.24	4.82	0.14	-0.45
	95% CI	3.96, 4.80	3.63, 4.85	4.10, 5.55	-0.60, 0.87	-1.27, 0.38
Day 30	n	39	32	13		
	LS Mean	4.53	4.55	3.01	-0.01	1.52
	95% CI	4.08, 4.99	4.05, 5.05	2.24, 3.78	-0.69, 0.66	0.64, 2.41
Day 60	n	39	32	11		
	LS Mean	4.91	5.16	2.93	-0.26	1.97
	95% CI	4.43, 5.39	4.64, 5.69	2.04, 3.83	-0.96, 0.45	0.97, 2.98
Day 90	n	46	27	7		
	LS Mean	4.46	4.72	2.73	-0.25	1.73
	95% CI	4.08, 4.85	4.22, 5.21	1.77, 3.70	-0.87, 0.37	0.70, 2.77

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Factor 2 - Relief						
Day 1	n	75	33	24		
	LS Mean	3.38	3.67	4.72	-0.29	-1.34
	95% CI	3.08, 3.68	3.22, 4.13	4.19, 5.25	-0.83, 0.24	-1.94, -0.73
Day 2	n	75	34	24		
	LS Mean	3.30	3.38	4.13	-0.09	-0.84
	95% CI	2.95, 3.64	2.88, 3.88	3.54, 4.73	-0.68, 0.51	-1.51, -0.16
Day 3	n	75	34	23		
	LS Mean	3.23	3.42	3.45	-0.18	-0.22
	95% CI	2.93, 3.53	2.98, 3.85	2.92, 3.98	-0.71, 0.34	-0.82, 0.39
Day 4	n	75	34	24		
	LS Mean	3.26	3.57	3.16	-0.32	0.10
	95% CI	2.90, 3.61	3.05, 4.09	2.54, 3.78	-0.94, 0.31	-0.61, 0.80

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Factor 2 - Relief (cont...)						
Day 5	n	75	34	24		
	LS Mean	3.14	3.43	3.29	-0.29	-0.15
	95% CI	2.82, 3.45	2.97, 3.89	2.74, 3.83	-0.84, 0.26	-0.77, 0.47
Day 30	n	39	32	13		
	LS Mean	2.95	3.79	1.92	-0.84	1.03
	95% CI	2.59, 3.30	3.40, 4.18	1.32, 2.52	-1.37, -0.31	0.33, 1.72
Day 60	n	39	32	11		
	LS Mean	3.03	3.86	2.06	-0.84	0.97
	95% CI	2.64, 3.41	3.44, 4.28	1.34, 2.78	-1.40, -0.27	0.16, 1.78
Day 90	n	46	27	7		
	LS Mean	3.00	3.33	2.11	-0.33	0.89
	95% CI	2.69, 3.31	2.93, 3.73	1.32, 2.90	-0.83, 0.17	0.04, 1.74

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Total Score						
Day 1	n	75	33	24		
	LS Mean	3.94	4.15	5.29	-0.21	-1.35
	95% CI	3.62, 4.27	3.67, 4.63	4.73, 5.85	-0.78, 0.36	-1.99, -0.70
Day 2	n	75	34	24		
	LS Mean	3.86	3.94	4.75	-0.09	-0.89
	95% CI	3.49, 4.22	3.40, 4.48	4.11, 5.39	-0.73, 0.56	-1.62, -0.16
Day 3	n	75	34	23		
	LS Mean	3.85	3.85	4.09	-0.01	-0.24
	95% CI	3.51, 4.18	3.37, 4.34	3.50, 4.68	-0.59, 0.58	-0.92, 0.43
Day 4	n	75	34	24		
	LS Mean	3.84	4.12	3.89	-0.27	-0.04
	95% CI	3.47, 4.22	3.57, 4.66	3.24, 4.53	-0.93, 0.38	-0.78, 0.70

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.53.1 Analysis of QSU-brief Factors and Total Scores - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Total Score (cont...)						
Day 5	n	75	34	24		
	LS Mean	3.76	3.84	4.04	-0.08	-0.29
	95% CI	3.41, 4.10	3.34, 4.34	3.45, 4.64	-0.68, 0.52	-0.97, 0.40
Day 30	n	39	32	13		
	LS Mean	3.75	4.18	2.42	-0.42	1.33
	95% CI	3.38, 4.13	3.77, 4.59	1.79, 3.05	-0.97, 0.13	0.61, 2.06
Day 60	n	39	32	11		
	LS Mean	3.97	4.52	2.48	-0.55	1.50
	95% CI	3.58, 4.36	4.09, 4.94	1.75, 3.20	-1.12, 0.03	0.68, 2.31
Day 90	n	46	27	7		
	LS Mean	3.74	4.02	2.41	-0.29	1.33
	95% CI	3.42, 4.05	3.62, 4.43	1.62, 3.20	-0.79, 0.22	0.48, 2.18

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Factor 1 - Reward						
Day 1	n	79	39	35		
	LS Mean	4.51	4.40	5.71	0.10	-1.20
	95% CI	4.14, 4.87	3.89, 4.92	5.16, 6.25	-0.52, 0.72	-1.85, -0.55
Day 2	n	79	40	34		
	LS Mean	4.34	4.41	5.22	-0.07	-0.88
	95% CI	3.93, 4.74	3.84, 4.97	4.60, 5.83	-0.76, 0.62	-1.61, -0.15
Day 3	n	79	40	33		
	LS Mean	4.45	4.16	4.66	0.29	-0.21
	95% CI	4.06, 4.84	3.62, 4.71	4.06, 5.26	-0.38, 0.95	-0.92, 0.50
Day 4	n	79	40	34		
	LS Mean	4.38	4.44	4.56	-0.06	-0.18
	95% CI	3.97, 4.78	3.87, 5.00	3.95, 5.17	-0.74, 0.63	-0.91, 0.55

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Factor 1 - Reward (cont...)						
Day 5	n	78	40	34		
	LS Mean	4.37	4.05	4.69	0.32	-0.32
	95% CI	3.96, 4.77	3.48, 4.61	4.07, 5.30	-0.37, 1.01	-1.05, 0.41
Day 30	n	76	38	33		
	LS Mean	4.65	4.27	3.64	0.39	1.01
	95% CI	4.29, 5.01	3.76, 4.77	3.10, 4.18	-0.23, 1.00	0.37, 1.66
Day 60	n	74	36	31		
	LS Mean	4.79	5.02	3.47	-0.22	1.33
	95% CI	4.45, 5.14	4.52, 5.51	2.94, 4.00	-0.82, 0.37	0.70, 1.95
Day 90	n	71	31	29		
	LS Mean	4.57	4.45	3.69	0.12	0.89
	95% CI	4.21, 4.94	3.90, 5.00	3.12, 4.25	-0.53, 0.77	0.22, 1.56

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Factor 2 - Relief						
Day 1	n	79	39	35		
	LS Mean	3.38	3.47	4.57	-0.09	-1.19
	95% CI	3.08, 3.68	3.04, 3.89	4.12, 5.02	-0.60, 0.43	-1.72, -0.66
Day 2	n	79	40	34		
	LS Mean	3.22	3.23	3.98	-0.01	-0.76
	95% CI	2.89, 3.55	2.78, 3.69	3.49, 4.47	-0.56, 0.54	-1.35, -0.18
Day 3	n	79	40	33		
	LS Mean	3.21	3.21	3.37	-0.01	-0.16
	95% CI	2.92, 3.50	2.81, 3.62	2.93, 3.82	-0.49, 0.48	-0.69, 0.36
Day 4	n	79	40	34		
	LS Mean	3.22	3.39	3.10	-0.17	0.13
	95% CI	2.88, 3.56	2.92, 3.86	2.58, 3.61	-0.74, 0.40	-0.48, 0.73

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Factor 2 - Relief (cont...)						
Day 5	n	78	40	34		
	LS Mean	3.13	3.24	3.22	-0.10	-0.09
	95% CI	2.82, 3.44	2.81, 3.66	2.75, 3.68	-0.63, 0.42	-0.64, 0.47
Day 30	n	76	38	33		
	LS Mean	3.13	3.38	2.27	-0.26	0.85
	95% CI	2.84, 3.41	2.99, 3.78	1.85, 2.70	-0.74, 0.22	0.35, 1.36
Day 60	n	74	36	31		
	LS Mean	2.99	3.61	2.35	-0.63	0.63
	95% CI	2.70, 3.27	3.20, 4.02	1.92, 2.79	-1.12, -0.14	0.11, 1.15
Day 90	n	71	31	29		
	LS Mean	3.00	3.16	2.46	-0.16	0.54
	95% CI	2.73, 3.27	2.75, 3.57	2.04, 2.88	-0.65, 0.32	0.04, 1.04

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Total Score						
Day 1	n	79	39	35		
	LS Mean	3.94	3.95	5.13	-0.01	-1.19
	95% CI	3.63, 4.25	3.51, 4.39	4.67, 5.60	-0.54, 0.52	-1.74, -0.64
Day 2	n	79	40	34		
	LS Mean	3.78	3.84	4.58	-0.06	-0.80
	95% CI	3.43, 4.13	3.35, 4.32	4.05, 5.12	-0.65, 0.54	-1.44, -0.17
Day 3	n	79	40	33		
	LS Mean	3.83	3.70	4.00	0.13	-0.17
	95% CI	3.51, 4.15	3.25, 4.15	3.51, 4.50	-0.41, 0.68	-0.76, 0.41
Day 4	n	79	40	34		
	LS Mean	3.80	3.92	3.81	-0.12	-0.01
	95% CI	3.45, 4.16	3.43, 4.42	3.28, 4.35	-0.72, 0.48	-0.65, 0.63

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.53.2 Analysis of QSU-brief Factors and Total Scores - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Total Score (cont...)						
Day 5	n	78	40	34		
	LS Mean	3.75	3.65	3.94	0.10	-0.19
	95% CI	3.41, 4.09	3.19, 4.12	3.44, 4.45	-0.47, 0.67	-0.80, 0.41
Day 30	n	76	38	33		
	LS Mean	3.89	3.84	2.94	0.06	0.95
	95% CI	3.59, 4.19	3.42, 4.26	2.49, 3.39	-0.45, 0.57	0.41, 1.49
Day 60	n	74	36	31		
	LS Mean	3.89	4.33	2.90	-0.43	1.00
	95% CI	3.60, 4.18	3.91, 4.74	2.45, 3.34	-0.93, 0.06	0.47, 1.52
Day 90	n	71	31	29		
	LS Mean	3.79	3.82	3.06	-0.02	0.74
	95% CI	3.49, 4.09	3.37, 4.27	2.60, 3.52	-0.56, 0.51	0.19, 1.28

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35	
	Mean (SD)	1.3 (0.93)		1.2 (0.46)	
	95% CI of Mean	1.1, 1.6		1.0, 1.4	
	Median	1.0		1.0	
	Q25, Q75	1.0, 1.5		1.0, 1.0	
	Min, Max	1, 7		1, 3	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 1	n	75	75	32	32
	Missing, n (%)	0	0	3 (8.6)	3 (8.6)
	Mean (SD)	1.4 (0.90)	15.2 (76.98)	1.4 (0.96)	21.3 (79.17)
	95% CI of Mean	1.1, 1.6	-2.6, 32.9	1.0, 1.8	-7.3, 49.8
	Median	1.0	0.0	1.0	0.0
	Q25, Q75	1.0, 1.0	0.0, 0.0	1.0, 1.0	0.0, 0.0
	Min, Max	1, 6	-86, 500	1, 5	-33, 400

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 2	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	1.3 (0.79)	8.3 (53.72)	1.1 (0.45)	-2.5 (13.81)
	95% CI of Mean	1.1, 1.5	-4.2, 20.7	0.9, 1.3	-7.4, 2.3
	Median	1.0	0.0	1.0	0.0
	Q25, Q75	1.0, 1.0	0.0, 0.0	1.0, 1.0	0.0, 0.0
	Min, Max	1, 5	-86, 300	1, 3	-33, 50

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 3	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	1.2 (0.69)	5.5 (57.31)	1.1 (0.49)	-1.3 (16.79)
	95% CI of Mean	1.0, 1.5	-7.7, 18.7	0.9, 1.4	-7.2, 4.6
	Median	1.0	0.0	1.0	0.0
	Q25, Q75	1.0, 1.0	0.0, 0.0	1.0, 1.0	0.0, 0.0
	Min, Max	1, 5	-86, 350	1, 4	-33, 75

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 4	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	1.2 (0.73)	5.1 (62.85)	1.1 (0.56)	-1.6 (21.15)
	95% CI of Mean	1.0, 1.5	-9.4, 19.6	0.9, 1.4	-9.0, 5.9
	Median	1.0	0.0	1.0	0.0
	Q25, Q75	1.0, 1.0	0.0, 0.0	1.0, 1.0	0.0, 0.0
	Min, Max	1, 6	-86, 450	1, 4	-33, 100

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 5	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	1.4 (0.96)	15.3 (84.15)	1.2 (0.57)	1.4 (23.79)
	95% CI of Mean	1.1, 1.6	-4.1, 34.8	0.9, 1.4	-7.0, 9.7
	Median	1.0	0.0	1.0	0.0
	Q25, Q75	1.0, 1.0	0.0, 0.0	1.0, 1.0	0.0, 0.0
	Min, Max	1, 6	-86, 500	1, 4	-50, 100

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34	
	Mean (SD)	1.5 (1.19)		1.2 (0.46)	
	95% CI of Mean	1.0, 1.9		1.0, 1.4	
	Median	1.0		1.0	
	Q25, Q75	1.0, 1.5		1.0, 1.0	
	Min, Max	1, 7		1, 3	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)	
		Value	% Change(*)	Value	% Change(*)
Day 30	n	39	39	33	33
	Missing, n (%)	1 (2.5)	1 (2.5)	1 (2.9)	1 (2.9)
	Mean (SD)	1.2 (0.57)	-3.0 (36.74)	1.2 (0.62)	1.4 (23.80)
	95% CI of Mean	1.0, 1.4	-14.9, 9.0	0.9, 1.5	-7.1, 9.9
	Median	1.0	0.0	1.0	0.0
	Q25, Q75	1.0, 1.0	0.0, 0.0	1.0, 1.0	0.0, 0.0
	Min, Max	1, 4	-86, 100	1, 4	-33, 100

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35	
	Mean (SD)	1.5 (1.21)		1.2 (0.46)	
	95% CI of Mean	1.0, 1.9		1.0, 1.4	
	Median	1.0		1.0	
	Q25, Q75	1.0, 1.5		1.0, 1.0	
	Min, Max	1, 7		1, 3	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set**

Parameter: Aversion Subscale
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	32	32
	Missing, n (%)	0	0	3 (8.6)	3 (8.6)
	Mean (SD)	1.1 (0.51)	-3.2 (58.81)	1.2 (0.59)	7.6 (31.07)
	95% CI of Mean	0.9, 1.3	-22.3, 15.9	1.0, 1.5	-3.7, 18.8
	Median	1.0	0.0	1.0	0.0
	Q25, Q75	1.0, 1.0	-33.3, 0.0	1.0, 1.0	0.0, 0.0
	Min, Max	1, 4	-86, 300	1, 4	-50, 100

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32	
	Mean (SD)	1.4 (1.11)		1.1 (0.41)	
	95% CI of Mean	1.0, 1.8		0.9, 1.3	
	Median	1.0		1.0	
	Q25, Q75	1.0, 1.5		1.0, 1.0	
	Min, Max	1, 7		1, 3	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Aversion Subscale****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)	
		Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	31	31
	Missing, n (%)	0	0	1 (3.1)	1 (3.1)
	Mean (SD)	1.2 (0.56)	4.6 (61.85)	1.1 (0.52)	2.4 (33.56)
	95% CI of Mean	1.0, 1.4	-13.6, 22.8	0.9, 1.4	-9.9, 14.8
	Median	1.0	0.0	1.0	0.0
	Q25, Q75	1.0, 1.0	0.0, 0.0	1.0, 1.0	0.0, 0.0
	Min, Max	1, 4	-86, 300	1, 4	-50, 150

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35	
	Mean (SD)	5.2 (1.46)		5.5 (1.94)	
	95% CI of Mean	4.9, 5.6		4.8, 6.2	
	Median	5.0		6.0	
	Q25, Q75	4.0, 7.0		5.0, 7.0	
	Min, Max	1, 7		1, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 1	n	75	75	32	32
	Missing, n (%)	0	0	3 (8.6)	3 (8.6)
	Mean (SD)	3.9 (1.77)	-22.7 (34.32)	5.7 (1.47)	27.9 (128.17)
	95% CI of Mean	3.4, 4.3	-30.6, -14.7	5.1, 6.3	-18.3, 74.2
	Median	4.0	-20.0	6.0	0.0
	Q25, Q75	3.0, 5.0	-42.9, 0.0	5.0, 7.0	-15.5, 8.3
	Min, Max	1, 7	-86, 100	2, 7	-71, 600

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 2	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	4.0 (1.87)	-21.4 (31.68)	5.6 (1.31)	27.9 (117.63)
	95% CI of Mean	3.5, 4.5	-28.8, -14.1	5.1, 6.1	-13.2, 69.0
	Median	4.0	-16.7	6.0	0.0
	Q25, Q75	2.0, 5.0	-42.9, 0.0	5.0, 7.0	-14.3, 0.0
	Min, Max	1, 7	-86, 40	2, 7	-33, 600

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 3	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	4.0 (1.84)	-20.0 (36.86)	5.8 (1.56)	22.1 (106.51)
	95% CI of Mean	3.6, 4.5	-28.5, -11.5	5.2, 6.4	-15.2, 59.3
	Median	4.0	-16.7	6.0	0.0
	Q25, Q75	3.0, 5.0	-40.0, 0.0	5.0, 7.0	-14.3, 16.7
	Min, Max	1, 7	-86, 150	1, 7	-29, 600

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 4	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	4.1 (1.88)	-18.6 (37.32)	5.4 (1.64)	17.4 (108.48)
	95% CI of Mean	3.6, 4.5	-27.2, -10.0	4.8, 6.1	-20.5, 55.3
	Median	4.0	-16.7	6.0	0.0
	Q25, Q75	2.0, 5.0	-42.9, 0.0	5.0, 7.0	-14.3, 0.0
	Min, Max	1, 7	-86, 100	1, 7	-57, 600

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 5	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	4.2 (1.77)	-15.0 (35.62)	5.6 (1.77)	10.3 (59.19)
	95% CI of Mean	3.8, 4.7	-23.3, -6.8	4.9, 6.2	-10.4, 31.0
	Median	4.0	-14.3	6.0	0.0
	Q25, Q75	3.0, 6.0	-33.3, 0.0	5.0, 7.0	-14.3, 16.7
	Min, Max	1, 7	-86, 100	1, 7	-71, 300

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34	
	Mean (SD)	5.0 (1.57)		5.5 (1.90)	
	95% CI of Mean	4.4, 5.5		4.8, 6.2	
	Median	5.0		6.0	
	Q25, Q75	4.0, 6.0		5.0, 7.0	
	Min, Max	1, 7		1, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)	
		Value	% Change(*)	Value	% Change(*)
Day 30	n	39	39	32	32
	Missing, n (%)	1 (2.5)	1 (2.5)	2 (5.9)	2 (5.9)
	Mean (SD)	4.9 (1.53)	15.3 (80.74)	5.6 (1.67)	13.8 (60.67)
	95% CI of Mean	4.4, 5.5	-10.9, 41.5	4.9, 6.2	-8.1, 35.7
	Median	5.0	0.0	6.0	0.0
	Q25, Q75	4.0, 6.0	-20.0, 20.0	5.0, 7.0	-7.1, 8.3
	Min, Max	1, 7	-75, 400	1, 7	-43, 300

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35	
	Mean (SD)	4.9 (1.64)		5.6 (1.89)	
	95% CI of Mean	4.3, 5.5		4.9, 6.3	
	Median	5.0		6.0	
	Q25, Q75	4.0, 6.0		5.0, 7.0	
	Min, Max	1, 7		1, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	32	32
	Missing, n (%)	0	0	3 (8.6)	3 (8.6)
	Mean (SD)	4.6 (1.67)	3.7 (52.38)	5.4 (1.65)	2.2 (58.09)
	95% CI of Mean	4.0, 5.2	-13.3, 20.7	4.7, 6.0	-18.8, 23.2
	Median	4.0	0.0	6.0	0.0
	Q25, Q75	4.0, 6.0	-20.0, 16.7	5.0, 6.5	-14.3, 0.0
	Min, Max	1, 7	-75, 200	1, 7	-80, 300

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32	
	Mean (SD)	5.0 (1.59)		5.8 (1.71)	
	95% CI of Mean	4.5, 5.5		5.1, 6.4	
	Median	5.0		6.0	
	Q25, Q75	4.0, 6.0		5.0, 7.0	
	Min, Max	1, 7		1, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Craving Reduction Subscale****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)	
		Value	% Change(*)	Value	% Change(*)
Day 90	n	46	46	31	31
	Missing, n (%)	1 (2.1)	1 (2.1)	1 (3.1)	1 (3.1)
	Mean (SD)	4.5 (1.58)	-0.2 (68.03)	5.5 (1.37)	7.5 (63.44)
	95% CI of Mean	4.0, 5.0	-20.5, 20.0	4.9, 6.0	-15.8, 30.9
	Median	4.5	0.0	6.0	-14.3
	Q25, Q75	4.0, 6.0	-25.0, 0.0	5.0, 6.0	-16.7, 0.0
	Min, Max	1, 7	-86, 400	1, 7	-43, 300

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35	
	Mean (SD)	4.2 (1.70)		5.0 (1.73)	
	95% CI of Mean	3.8, 4.7		4.4, 5.7	
	Median	4.0		5.0	
	Q25, Q75	3.0, 6.0		4.0, 7.0	
	Min, Max	1, 7		1, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 1	n	75	75	32	32
	Missing, n (%)	0	0	3 (8.6)	3 (8.6)
	Mean (SD)	3.3 (1.88)	-16.7 (45.71)	4.9 (1.67)	2.4 (41.28)
	95% CI of Mean	2.8, 3.7	-27.3, -6.2	4.3, 5.6	-12.5, 17.4
	Median	3.0	0.0	5.0	0.0
	Q25, Q75	2.0, 4.0	-50.0, 0.0	4.0, 7.0	-16.7, 0.0
	Min, Max	1, 7	-83, 200	2, 7	-40, 200

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 2	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	3.6 (1.82)	-7.1 (56.79)	4.9 (1.98)	7.9 (74.94)
	95% CI of Mean	3.1, 4.0	-20.2, 6.0	4.2, 5.7	-18.3, 34.1
	Median	3.0	0.0	5.0	0.0
	Q25, Q75	2.0, 5.0	-33.3, 0.0	4.0, 7.0	0.0, 0.0
	Min, Max	1, 7	-83, 300	1, 7	-83, 400

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 3	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	3.5 (1.87)	-9.4 (62.72)	5.2 (1.65)	15.2 (71.36)
	95% CI of Mean	3.0, 3.9	-23.9, 5.1	4.6, 5.8	-9.8, 40.1
	Median	4.0	0.0	5.5	0.0
	Q25, Q75	2.0, 4.0	-50.0, 0.0	4.0, 7.0	0.0, 0.0
	Min, Max	1, 7	-83, 300	1, 7	-40, 400

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 4	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	3.6 (1.98)	-5.3 (58.36)	4.8 (2.02)	10.5 (109.13)
	95% CI of Mean	3.1, 4.1	-18.8, 8.2	4.0, 5.5	-27.7, 48.6
	Median	3.0	0.0	5.0	0.0
	Q25, Q75	2.0, 5.0	-33.3, 0.0	3.0, 7.0	-28.6, 0.0
	Min, Max	1, 7	-86, 300	1, 7	-75, 600

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 5	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	3.8 (1.92)	1.3 (74.93)	4.9 (1.98)	2.6 (43.55)
	95% CI of Mean	3.3, 4.3	-16.0, 18.6	4.2, 5.7	-12.7, 17.8
	Median	4.0	0.0	6.0	0.0
	Q25, Q75	2.0, 5.0	-33.3, 0.0	3.0, 7.0	0.0, 0.0
	Min, Max	1, 7	-83, 400	1, 7	-67, 200

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34	
	Mean (SD)	4.5 (1.62)		4.9 (1.72)	
	95% CI of Mean	4.0, 5.1		4.3, 5.6	
	Median	4.0		5.0	
	Q25, Q75	4.0, 6.0		4.0, 6.0	
	Min, Max	1, 7		1, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set**

Parameter: Enjoyment of Respiratory Tract Sensation Subscale
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)	
		Value	% Change(*)	Value	% Change(*)
Day 30	n	39	39	33	33
	Missing, n (%)	1 (2.5)	1 (2.5)	1 (2.9)	1 (2.9)
	Mean (SD)	4.6 (1.47)	26.0 (98.33)	5.0 (1.65)	15.5 (74.88)
	95% CI of Mean	4.0, 5.1	-5.9, 57.9	4.4, 5.7	-11.1, 42.1
	Median	4.0	0.0	5.0	0.0
	Q25, Q75	4.0, 6.0	-25.0, 25.0	4.0, 6.0	-14.3, 16.7
	Min, Max	1, 7	-83, 400	2, 7	-40, 400

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35	
	Mean (SD)	4.3 (1.67)		5.0 (1.73)	
	95% CI of Mean	3.7, 4.8		4.3, 5.6	
	Median	4.0		5.0	
	Q25, Q75	3.0, 6.0		4.0, 7.0	
	Min, Max	1, 7		1, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	32	32
	Missing, n (%)	0	0	3 (8.6)	3 (8.6)
	Mean (SD)	4.3 (1.54)	23.8 (98.21)	5.0 (1.55)	1.9 (24.91)
	95% CI of Mean	3.7, 4.8	-8.1, 55.7	4.4, 5.6	-7.1, 11.0
	Median	4.0	0.0	5.0	0.0
	Q25, Q75	3.0, 5.0	-20.0, 25.0	4.0, 6.0	0.0, 0.0
	Min, Max	1, 7	-60, 400	2, 7	-40, 100

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32	
	Mean (SD)	4.3 (1.61)		5.1 (1.61)	
	95% CI of Mean	3.8, 4.8		4.4, 5.7	
	Median	4.0		5.0	
	Q25, Q75	3.0, 6.0		4.0, 6.5	
	Min, Max	1, 7		1, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Enjoyment of Respiratory Tract Sensation Subscale****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)	
		Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	31	31
	Missing, n (%)	0	0	1 (3.1)	1 (3.1)
	Mean (SD)	4.4 (1.44)	24.2 (97.83)	4.9 (1.72)	2.6 (43.38)
	95% CI of Mean	3.9, 4.9	-4.6, 53.0	4.3, 5.6	-13.4, 18.5
	Median	4.0	0.0	5.0	0.0
	Q25, Q75	4.0, 5.0	-25.0, 25.0	3.0, 6.0	-14.3, 0.0
	Min, Max	1, 7	-50, 400	1, 7	-67, 200

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35	
	Mean (SD)	4.0 (1.58)		4.1 (1.73)	
	95% CI of Mean	3.6, 4.4		3.5, 4.8	
	Median	4.2		4.6	
	Q25, Q75	2.6, 5.0		2.4, 5.6	
	Min, Max	1, 7		1, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 1	n	75	75	32	32
	Missing, n (%)	0	0	3 (8.6)	3 (8.6)
	Mean (SD)	3.1 (1.66)	-22.6 (25.26)	4.2 (1.51)	7.8 (50.12)
	95% CI of Mean	2.6, 3.5	-28.5, -16.8	3.6, 4.8	-10.3, 25.9
	Median	3.0	-19.2	4.3	-3.8
	Q25, Q75	1.6, 4.2	-43.3, 0.0	3.1, 5.1	-18.9, 7.5
	Min, Max	1, 7	-78, 29	1, 7	-52, 218

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 2	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	3.0 (1.60)	-22.4 (25.99)	3.9 (1.66)	-4.0 (34.52)
	95% CI of Mean	2.6, 3.5	-28.4, -16.3	3.3, 4.5	-16.1, 8.0
	Median	3.0	-20.0	4.0	-7.6
	Q25, Q75	1.6, 4.0	-37.5, 0.0	2.6, 5.0	-27.8, 4.3
	Min, Max	1, 7	-78, 50	1, 7	-52, 118

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set**

Parameter: Psychological Reward Subscale
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 3	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	3.1 (1.63)	-20.4 (28.07)	3.8 (1.68)	-6.5 (32.96)
	95% CI of Mean	2.7, 3.5	-26.9, -13.9	3.1, 4.4	-18.0, 5.1
	Median	3.0	-17.6	3.8	-10.0
	Q25, Q75	1.8, 4.2	-42.9, 0.0	2.2, 5.0	-25.8, 5.6
	Min, Max	1, 7	-76, 64	1, 7	-61, 82

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 4	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	3.1 (1.69)	-21.6 (27.13)	3.8 (1.65)	-3.1 (50.36)
	95% CI of Mean	2.7, 3.6	-27.9, -15.3	3.2, 4.4	-20.7, 14.5
	Median	3.0	-20.0	3.9	-9.9
	Q25, Q75	1.6, 4.2	-40.0, 0.0	2.4, 5.0	-27.8, 9.4
	Min, Max	1, 7	-76, 36	1, 7	-52, 233

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 5	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	3.1 (1.67)	-20.8 (28.14)	3.7 (1.84)	-10.5 (33.37)
	95% CI of Mean	2.7, 3.5	-27.4, -14.3	3.0, 4.4	-22.2, 1.2
	Median	3.0	-20.0	3.8	-12.4
	Q25, Q75	1.6, 4.2	-43.8, 0.0	1.8, 5.2	-33.3, 4.2
	Min, Max	1, 7	-81, 50	1, 7	-70, 82

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34	
	Mean (SD)	4.2 (1.53)		4.1 (1.66)	
	95% CI of Mean	3.7, 4.7		3.5, 4.7	
	Median	4.4		4.5	
	Q25, Q75	3.1, 5.2		2.4, 5.4	
	Min, Max	1, 7		1, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)	
		Value	% Change(*)	Value	% Change(*)
Day 30	n	39	39	33	33
	Missing, n (%)	1 (2.5)	1 (2.5)	1 (2.9)	1 (2.9)
	Mean (SD)	3.8 (1.24)	-1.2 (50.64)	4.0 (1.73)	3.3 (41.90)
	95% CI of Mean	3.3, 4.2	-17.7, 15.2	3.3, 4.6	-11.6, 18.2
	Median	4.0	-12.0	3.8	0.0
	Q25, Q75	3.0, 4.6	-28.1, 4.5	2.6, 5.4	-17.4, 11.1
	Min, Max	1, 7	-57, 233	1, 7	-71, 164

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35	
	Mean (SD)	4.2 (1.41)		4.2 (1.70)	
	95% CI of Mean	3.7, 4.7		3.5, 4.8	
	Median	4.4		4.6	
	Q25, Q75	3.2, 5.0		2.4, 5.6	
	Min, Max	1, 7		1, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	32	32
	Missing, n (%)	0	0	3 (8.6)	3 (8.6)
	Mean (SD)	3.5 (1.24)	-9.4 (32.58)	3.8 (1.68)	-6.3 (49.52)
	95% CI of Mean	3.1, 4.0	-20.0, 1.2	3.1, 4.5	-24.2, 11.6
	Median	3.4	-14.3	4.0	-9.6
	Q25, Q75	2.4, 4.4	-31.3, 4.5	2.4, 5.0	-36.1, 4.7
	Min, Max	1, 7	-62, 100	1, 7	-57, 218

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Psychological Reward Subscale****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32	
	Mean (SD)	4.2 (1.46)		4.4 (1.60)	
	95% CI of Mean	3.8, 4.7		3.8, 5.0	
	Median	4.4		4.6	
	Q25, Q75	3.2, 5.2		3.4, 5.7	
	Min, Max	1, 7		1, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set**

Parameter: Psychological Reward Subscale
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)	
		Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	31	31
	Missing, n (%)	0	0	1 (3.1)	1 (3.1)
	Mean (SD)	3.5 (1.39)	-12.4 (36.51)	3.8 (1.61)	-10.5 (26.92)
	95% CI of Mean	3.0, 3.9	-23.2, -1.6	3.2, 4.5	-20.5, -0.6
	Median	3.4	-17.9	3.8	-12.5
	Q25, Q75	2.4, 4.6	-33.3, 0.0	2.6, 4.8	-27.8, 0.0
	Min, Max	1, 7	-76, 117	1, 7	-50, 82

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35	
	Mean (SD)	5.1 (1.33)		5.8 (1.41)	
	95% CI of Mean	4.8, 5.5		5.2, 6.3	
	Median	5.0		6.3	
	Q25, Q75	4.0, 6.3		5.0, 7.0	
	Min, Max	2, 7		2, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 1	n	75	75	32	32
	Missing, n (%)	0	0	3 (8.6)	3 (8.6)
	Mean (SD)	3.9 (1.70)	-24.4 (26.08)	5.7 (1.27)	5.4 (43.42)
	95% CI of Mean	3.4, 4.3	-30.5, -18.4	5.2, 6.2	-10.3, 21.1
	Median	4.0	-18.6	6.0	0.0
	Q25, Q75	2.7, 5.0	-41.3, 0.0	4.7, 7.0	-6.3, 2.5
	Min, Max	1, 7	-86, 25	3, 7	-35, 235

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 2	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	4.2 (1.58)	-16.7 (25.54)	5.8 (1.28)	7.6 (47.80)
	95% CI of Mean	3.8, 4.6	-22.7, -10.8	5.3, 6.3	-9.1, 24.3
	Median	4.0	-10.8	6.3	0.0
	Q25, Q75	3.0, 5.3	-29.8, 0.0	4.7, 7.0	-4.8, 5.3
	Min, Max	1, 7	-86, 30	3, 7	-35, 271

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 3	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	4.3 (1.55)	-14.6 (26.88)	5.8 (1.32)	8.3 (48.82)
	95% CI of Mean	3.8, 4.7	-20.9, -8.4	5.3, 6.3	-8.8, 25.4
	Median	4.0	-14.0	6.2	0.0
	Q25, Q75	3.3, 5.0	-25.4, 0.0	5.0, 7.0	-4.3, 5.3
	Min, Max	1, 7	-86, 33	3, 7	-42, 271

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 4	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	4.3 (1.72)	-14.7 (28.68)	5.7 (1.36)	7.7 (56.77)
	95% CI of Mean	3.8, 4.7	-21.4, -8.1	5.2, 6.3	-12.2, 27.5
	Median	4.0	-7.5	6.2	0.0
	Q25, Q75	3.0, 5.7	-29.9, 0.0	5.0, 7.0	-10.8, 11.1
	Min, Max	1, 7	-86, 58	3, 7	-47, 312

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 5	n	75	75	34	34
	Missing, n (%)	0	0	1 (2.9)	1 (2.9)
	Mean (SD)	4.4 (1.64)	-12.7 (26.91)	5.8 (1.39)	4.5 (33.16)
	95% CI of Mean	4.0, 4.8	-18.9, -6.4	5.2, 6.3	-7.1, 16.1
	Median	4.3	-7.0	6.2	0.0
	Q25, Q75	3.3, 5.3	-21.7, 0.0	4.7, 7.0	-7.5, 10.0
	Min, Max	1, 7	-86, 47	3, 7	-47, 176

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34	
	Mean (SD)	5.2 (1.30)		5.7 (1.42)	
	95% CI of Mean	4.7, 5.6		5.2, 6.3	
	Median	5.2		6.3	
	Q25, Q75	4.3, 6.3		5.0, 7.0	
	Min, Max	2, 7		2, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)	
		Value	% Change(*)	Value	% Change(*)
Day 30	n	39	39	33	33
	Missing, n (%)	1 (2.5)	1 (2.5)	1 (2.9)	1 (2.9)
	Mean (SD)	5.0 (1.28)	-3.3 (23.10)	5.7 (1.42)	0.6 (13.12)
	95% CI of Mean	4.5, 5.4	-10.8, 4.3	5.1, 6.2	-4.1, 5.3
	Median	5.0	0.0	6.0	0.0
	Q25, Q75	4.0, 6.0	-16.7, 9.3	4.0, 7.0	-4.3, 6.3
	Min, Max	1, 7	-63, 43	2, 7	-30, 33

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35	
	Mean (SD)	5.0 (1.33)		5.8 (1.41)	
	95% CI of Mean	4.5, 5.5		5.2, 6.3	
	Median	5.0		6.3	
	Q25, Q75	4.0, 6.0		5.0, 7.0	
	Min, Max	2, 7		2, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)	
		Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	32	32
	Missing, n (%)	0	0	3 (8.6)	3 (8.6)
	Mean (SD)	4.6 (1.32)	-5.6 (23.06)	5.5 (1.50)	-6.2 (19.86)
	95% CI of Mean	4.1, 5.1	-13.2, 1.9	4.9, 6.1	-13.4, 1.0
	Median	4.7	-5.7	6.0	-2.1
	Q25, Q75	4.0, 5.3	-20.0, 6.4	4.4, 6.7	-14.9, 3.2
	Min, Max	2, 7	-57, 43	1, 7	-84, 33

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set****Parameter: Smoking Satisfaction Subscale****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32	
	Mean (SD)	5.1 (1.32)		5.9 (1.22)	
	95% CI of Mean	4.6, 5.5		5.4, 6.4	
	Median	5.0		6.3	
	Q25, Q75	4.0, 6.0		5.0, 7.0	
	Min, Max	2, 7		3, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.1 Descriptive Statistics of MCEQ subscales - PP Set**

Parameter: Smoking Satisfaction Subscale
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)	
		Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	31	31
	Missing, n (%)	0	0	1 (3.1)	1 (3.1)
	Mean (SD)	4.8 (1.38)	-3.2 (26.63)	5.7 (1.36)	-2.3 (18.74)
	95% CI of Mean	4.3, 5.2	-11.1, 4.7	5.1, 6.2	-9.2, 4.7
	Median	4.7	-5.7	6.3	0.0
	Q25, Q75	4.0, 6.0	-21.7, 13.2	4.3, 7.0	-10.0, 0.0
	Min, Max	1, 7	-52, 104	3, 7	-36, 73

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Aversion Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41	
	Mean (SD)	1.3 (0.90)		1.1 (0.43)	
	95% CI of Mean	1.1, 1.6		1.0, 1.3	
	Median	1.0		1.0	
	Q25, Q75	1.0, 1.3		1.0, 1.0	
	Min, Max	1, 7		1, 3	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Aversion Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 1	n	80	80	38	38
	Missing, n (%)	0	0	3 (7.3)	3 (7.3)
	Mean (SD)	1.4 (0.88)	15.9 (75.20)	1.3 (0.89)	17.9 (72.89)
	95% CI of Mean	1.1, 1.6	-0.9, 32.7	1.0, 1.7	-6.1, 41.9
	Median	1.0	0.0	1.0	0.0
	Q25, Q75	1.0, 1.0	0.0, 0.0	1.0, 1.0	0.0, 0.0
	Min, Max	1, 6	-86, 500	1, 5	-33, 400

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Aversion Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 2	n	80	80	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)
	Mean (SD)	1.3 (0.77)	7.3 (52.23)	1.1 (0.42)	-2.2 (12.74)
	95% CI of Mean	1.1, 1.5	-4.3, 19.0	0.9, 1.3	-6.3, 2.0
	Median	1.0	0.0	1.0	0.0
	Q25, Q75	1.0, 1.0	0.0, 0.0	1.0, 1.0	0.0, 0.0
	Min, Max	1, 5	-86, 300	1, 3	-33, 50

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Aversion Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 3	n	80	80	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)
	Mean (SD)	1.2 (0.67)	5.2 (55.48)	1.1 (0.45)	-1.1 (15.45)
	95% CI of Mean	1.0, 1.4	-7.2, 17.6	0.9, 1.3	-6.1, 3.9
	Median	1.0	0.0	1.0	0.0
	Q25, Q75	1.0, 1.0	0.0, 0.0	1.0, 1.0	0.0, 0.0
	Min, Max	1, 5	-86, 350	1, 4	-33, 75

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Aversion Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 4	n	80	80	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)
	Mean (SD)	1.2 (0.71)	4.8 (60.84)	1.1 (0.52)	-1.3 (19.47)
	95% CI of Mean	1.0, 1.4	-8.8, 18.4	0.9, 1.3	-7.6, 4.9
	Median	1.0	0.0	1.0	0.0
	Q25, Q75	1.0, 1.0	0.0, 0.0	1.0, 1.0	0.0, 0.0
	Min, Max	1, 6	-86, 450	1, 4	-33, 100

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Aversion Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 5	n	79	79	40	40
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Mean (SD)	1.3 (0.94)	14.1 (82.20)	1.2 (0.53)	1.2 (21.89)
	95% CI of Mean	1.1, 1.6	-4.3, 32.6	0.9, 1.4	-5.9, 8.2
	Median	1.0	0.0	1.0	0.0
	Q25, Q75	1.0, 1.0	0.0, 0.0	1.0, 1.0	0.0, 0.0
	Min, Max	1, 6	-86, 500	1, 4	-50, 100

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Aversion Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 30	n	76	76	39	39
	Missing, n (%)	4 (5.0)	4 (5.0)	2 (4.9)	2 (4.9)
	Mean (SD)	1.2 (0.51)	-0.2 (34.74)	1.2 (0.57)	1.2 (21.84)
	95% CI of Mean	1.0, 1.3	-8.2, 7.8	0.9, 1.4	-5.9, 8.3
	Median	1.0	0.0	1.0	0.0
	Q25, Q75	1.0, 1.0	0.0, 0.0	1.0, 1.0	0.0, 0.0
	Min, Max	1, 4	-86, 100	1, 4	-33, 100

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Aversion Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 60	n	74	74	36	36
	Missing, n (%)	6 (7.5)	6 (7.5)	5 (12.2)	5 (12.2)
	Mean (SD)	1.2 (0.60)	2.9 (58.02)	1.2 (0.56)	8.1 (30.18)
	95% CI of Mean	1.0, 1.4	-10.6, 16.4	1.0, 1.4	-2.2, 18.4
	Median	1.0	0.0	1.0	0.0
	Q25, Q75	1.0, 1.0	0.0, 0.0	1.0, 1.0	0.0, 0.0
	Min, Max	1, 4	-86, 300	1, 4	-50, 100

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Aversion Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 90	n	73	73	35	35
	Missing, n (%)	7 (8.8)	7 (8.8)	6 (14.6)	6 (14.6)
	Mean (SD)	1.2 (0.54)	5.0 (59.11)	1.1 (0.50)	2.1 (31.53)
	95% CI of Mean	1.0, 1.4	-8.8, 18.9	0.9, 1.3	-8.7, 13.0
	Median	1.0	0.0	1.0	0.0
	Q25, Q75	1.0, 1.0	0.0, 0.0	1.0, 1.0	0.0, 0.0
	Min, Max	1, 4	-86, 300	1, 4	-50, 150

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Craving Reduction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41	
	Mean (SD)	5.3 (1.46)		5.6 (1.82)	
	95% CI of Mean	4.9, 5.7		5.0, 6.2	
	Median	5.0		6.0	
	Q25, Q75	4.0, 7.0		5.0, 7.0	
	Min, Max	1, 7		1, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Craving Reduction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 1	n	80	80	38	38
	Missing, n (%)	0	0	3 (7.3)	3 (7.3)
	Mean (SD)	3.9 (1.83)	-23.6 (34.88)	5.8 (1.41)	23.7 (117.90)
	95% CI of Mean	3.4, 4.3	-31.5, -15.8	5.3, 6.3	-15.1, 62.5
	Median	4.0	-20.0	6.0	0.0
	Q25, Q75	3.0, 5.0	-46.4, 0.0	5.0, 7.0	-14.3, 16.7
	Min, Max	1, 7	-86, 100	2, 7	-71, 600

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Craving Reduction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 2	n	80	80	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)
	Mean (SD)	4.1 (1.91)	-20.3 (31.02)	5.4 (1.60)	18.0 (111.65)
	95% CI of Mean	3.7, 4.6	-27.3, -13.4	4.8, 5.9	-17.7, 53.8
	Median	4.0	-14.3	6.0	0.0
	Q25, Q75	3.0, 5.5	-33.3, 0.0	4.5, 6.5	-14.3, 0.0
	Min, Max	1, 7	-86, 40	1, 7	-80, 600

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Craving Reduction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 3	n	80	80	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)
	Mean (SD)	4.1 (1.86)	-19.5 (35.97)	5.6 (1.69)	15.3 (100.16)
	95% CI of Mean	3.7, 4.6	-27.6, -11.5	5.0, 6.2	-16.8, 47.3
	Median	4.0	-16.7	6.0	0.0
	Q25, Q75	3.0, 5.5	-40.0, 0.0	5.0, 7.0	-14.3, 8.3
	Min, Max	1, 7	-86, 150	1, 7	-80, 600

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Craving Reduction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 4	n	80	80	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)
	Mean (SD)	4.2 (1.89)	-18.2 (36.40)	5.4 (1.62)	12.4 (101.19)
	95% CI of Mean	3.7, 4.6	-26.4, -10.1	4.8, 5.9	-20.1, 44.8
	Median	4.0	-15.5	6.0	0.0
	Q25, Q75	3.0, 6.0	-42.9, 0.0	5.0, 6.5	-14.3, 0.0
	Min, Max	1, 7	-86, 100	1, 7	-57, 600

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Craving Reduction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 5	n	79	79	40	40
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Mean (SD)	4.3 (1.77)	-14.7 (34.78)	5.5 (1.76)	5.7 (56.60)
	95% CI of Mean	3.9, 4.8	-22.5, -6.9	4.8, 6.1	-12.5, 23.8
	Median	4.0	-14.3	6.0	0.0
	Q25, Q75	3.0, 6.0	-33.3, 0.0	4.0, 7.0	-14.3, 8.3
	Min, Max	1, 7	-86, 100	1, 7	-71, 300

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Craving Reduction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 30	n	76	76	38	38
	Missing, n (%)	4 (5.0)	4 (5.0)	3 (7.3)	3 (7.3)
	Mean (SD)	4.8 (1.60)	-1.1 (63.79)	5.6 (1.55)	10.1 (56.39)
	95% CI of Mean	4.3, 5.2	-15.8, 13.5	5.1, 6.2	-8.5, 28.7
	Median	5.0	0.0	6.0	0.0
	Q25, Q75	4.0, 6.0	-28.6, 8.3	5.0, 7.0	-14.3, 0.0
	Min, Max	1, 7	-86, 400	1, 7	-43, 300

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Craving Reduction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 60	n	74	74	36	36
	Missing, n (%)	6 (7.5)	6 (7.5)	5 (12.2)	5 (12.2)
	Mean (SD)	4.6 (1.78)	-6.8 (46.04)	5.3 (1.59)	-0.9 (55.68)
	95% CI of Mean	4.2, 5.1	-17.5, 3.9	4.7, 5.9	-19.8, 18.0
	Median	5.0	0.0	6.0	0.0
	Q25, Q75	4.0, 6.0	-33.3, 0.0	4.5, 6.0	-16.7, 0.0
	Min, Max	1, 7	-86, 200	1, 7	-80, 300

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Craving Reduction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 90	n	72	72	35	35
	Missing, n (%)	8 (10.0)	8 (10.0)	6 (14.6)	6 (14.6)
	Mean (SD)	4.4 (1.61)	-9.7 (57.59)	5.4 (1.34)	4.4 (60.39)
	95% CI of Mean	4.0, 4.9	-23.2, 3.9	4.9, 5.9	-16.4, 25.2
	Median	4.0	0.0	6.0	-14.3
	Q25, Q75	4.0, 6.0	-33.3, 0.0	5.0, 6.0	-16.7, 0.0
	Min, Max	1, 7	-86, 400	1, 7	-43, 300

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41	
	Mean (SD)	4.3 (1.73)		4.9 (1.71)	
	95% CI of Mean	3.9, 4.7		4.3, 5.5	
	Median	4.0		5.0	
	Q25, Q75	3.0, 6.0		4.0, 6.0	
	Min, Max	1, 7		1, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 1	n	80	80	38	38
	Missing, n (%)	0	0	3 (7.3)	3 (7.3)
	Mean (SD)	3.3 (1.87)	-17.6 (45.45)	4.7 (1.69)	1.1 (41.54)
	95% CI of Mean	2.8, 3.7	-27.8, -7.5	4.1, 5.3	-12.6, 14.8
	Median	3.0	0.0	4.5	0.0
	Q25, Q75	2.0, 4.0	-50.0, 0.0	4.0, 6.0	-16.7, 0.0
	Min, Max	1, 7	-86, 200	1, 7	-75, 200

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 2	n	80	80	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)
	Mean (SD)	3.6 (1.81)	-7.5 (55.53)	4.6 (2.07)	2.7 (71.86)
	95% CI of Mean	3.1, 4.1	-19.9, 4.9	3.9, 5.3	-20.3, 25.7
	Median	3.5	0.0	5.0	0.0
	Q25, Q75	2.0, 5.0	-33.3, 0.0	3.0, 6.5	-16.7, 0.0
	Min, Max	1, 7	-83, 300	1, 7	-86, 400

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 3	n	80	80	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)
	Mean (SD)	3.5 (1.87)	-8.9 (61.04)	5.0 (1.60)	13.5 (66.96)
	95% CI of Mean	3.1, 4.0	-22.6, 4.7	4.5, 5.6	-8.0, 35.0
	Median	4.0	0.0	5.0	0.0
	Q25, Q75	2.0, 4.5	-42.9, 0.0	4.0, 6.5	0.0, 0.0
	Min, Max	1, 7	-83, 300	1, 7	-43, 400

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 4	n	80	80	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)
	Mean (SD)	3.7 (1.99)	-5.6 (57.38)	4.7 (1.89)	9.5 (101.20)
	95% CI of Mean	3.2, 4.2	-18.4, 7.2	4.0, 5.3	-22.9, 41.9
	Median	3.0	0.0	5.0	0.0
	Q25, Q75	2.0, 5.0	-33.3, 0.0	3.5, 6.0	-22.6, 0.0
	Min, Max	1, 7	-86, 300	1, 7	-75, 600

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 5	n	79	79	40	40
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Mean (SD)	3.8 (1.89)	0.2 (73.31)	4.8 (1.88)	2.6 (42.96)
	95% CI of Mean	3.3, 4.3	-16.3, 16.6	4.1, 5.4	-11.2, 16.4
	Median	4.0	0.0	4.5	0.0
	Q25, Q75	2.0, 5.0	-33.3, 0.0	3.0, 6.5	0.0, 0.0
	Min, Max	1, 7	-83, 400	1, 7	-67, 200

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 30	n	76	76	39	39
	Missing, n (%)	4 (5.0)	4 (5.0)	2 (4.9)	2 (4.9)
	Mean (SD)	4.2 (1.65)	15.4 (84.06)	4.8 (1.70)	12.5 (71.64)
	95% CI of Mean	3.8, 4.6	-3.9, 34.6	4.2, 5.4	-10.8, 35.8
	Median	4.0	0.0	5.0	0.0
	Q25, Q75	3.0, 5.0	-25.0, 22.5	4.0, 6.0	-16.7, 20.0
	Min, Max	1, 7	-83, 400	1, 7	-86, 400

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 60	n	74	74	36	36
	Missing, n (%)	6 (7.5)	6 (7.5)	5 (12.2)	5 (12.2)
	Mean (SD)	4.2 (1.69)	15.7 (85.10)	4.8 (1.66)	-0.7 (28.25)
	95% CI of Mean	3.7, 4.6	-4.0, 35.5	4.2, 5.4	-10.3, 9.0
	Median	4.0	0.0	5.0	0.0
	Q25, Q75	3.0, 5.0	-20.0, 20.0	3.5, 6.0	-7.1, 0.0
	Min, Max	1, 7	-83, 400	1, 7	-86, 100

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Enjoyment of Respiratory Tract Sensation Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 90	n	73	73	35	35
	Missing, n (%)	7 (8.8)	7 (8.8)	6 (14.6)	6 (14.6)
	Mean (SD)	4.2 (1.73)	14.2 (84.96)	4.9 (1.65)	3.0 (43.35)
	95% CI of Mean	3.8, 4.7	-5.6, 34.1	4.2, 5.5	-12.0, 17.9
	Median	4.0	0.0	5.0	0.0
	Q25, Q75	4.0, 5.0	-25.0, 16.7	3.0, 6.0	-14.3, 0.0
	Min, Max	1, 7	-86, 400	1, 7	-67, 200

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Psychological Reward Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41	
	Mean (SD)	4.0 (1.55)		4.1 (1.68)	
	95% CI of Mean	3.6, 4.4		3.5, 4.6	
	Median	4.2		4.4	
	Q25, Q75	2.7, 5.1		2.4, 5.2	
	Min, Max	1, 7		1, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Psychological Reward Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 1	n	80	80	38	38
	Missing, n (%)	0	0	3 (7.3)	3 (7.3)
	Mean (SD)	3.0 (1.64)	-23.7 (26.20)	4.0 (1.53)	5.3 (48.24)
	95% CI of Mean	2.6, 3.4	-29.6, -17.9	3.5, 4.6	-10.7, 21.2
	Median	2.9	-19.6	4.1	-3.8
	Q25, Q75	1.5, 4.1	-46.7, -3.8	3.0, 5.0	-18.5, 9.1
	Min, Max	1, 7	-84, 29	1, 7	-81, 218

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Psychological Reward Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 2	n	80	80	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)
	Mean (SD)	3.1 (1.62)	-22.0 (25.78)	3.7 (1.67)	-7.5 (35.32)
	95% CI of Mean	2.7, 3.5	-27.7, -16.2	3.1, 4.2	-18.9, 3.8
	Median	3.0	-19.6	3.8	-8.9
	Q25, Q75	1.6, 4.0	-36.9, 0.0	2.2, 4.8	-29.0, 2.2
	Min, Max	1, 7	-78, 50	1, 7	-81, 118

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Psychological Reward Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 3	n	80	80	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)
	Mean (SD)	3.1 (1.60)	-20.4 (27.54)	3.6 (1.67)	-9.4 (32.72)
	95% CI of Mean	2.7, 3.5	-26.5, -14.2	3.0, 4.2	-19.9, 1.1
	Median	3.0	-18.1	3.8	-13.2
	Q25, Q75	1.8, 4.1	-42.6, 0.0	2.0, 4.6	-25.4, 2.6
	Min, Max	1, 7	-76, 64	1, 7	-81, 82

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Psychological Reward Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 4	n	80	80	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)
	Mean (SD)	3.2 (1.64)	-21.4 (26.45)	3.6 (1.67)	-7.1 (48.30)
	95% CI of Mean	2.7, 3.6	-27.3, -15.5	3.0, 4.2	-22.6, 8.4
	Median	3.1	-19.6	3.7	-16.5
	Q25, Q75	1.6, 4.1	-38.8, 0.0	2.1, 4.8	-30.6, 8.7
	Min, Max	1, 7	-76, 36	1, 7	-81, 233

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Psychological Reward Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 5	n	79	79	40	40
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Mean (SD)	3.1 (1.65)	-20.6 (27.80)	3.6 (1.85)	-11.1 (34.35)
	95% CI of Mean	2.7, 3.6	-26.9, -14.4	2.9, 4.2	-22.1, -0.1
	Median	3.0	-19.0	3.5	-12.4
	Q25, Q75	1.8, 4.2	-43.8, 0.0	1.8, 5.1	-35.4, 4.9
	Min, Max	1, 7	-81, 50	1, 7	-81, 82

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Psychological Reward Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 30	n	76	76	39	39
	Missing, n (%)	4 (5.0)	4 (5.0)	2 (4.9)	2 (4.9)
	Mean (SD)	3.6 (1.43)	-5.7 (43.64)	4.0 (1.73)	2.7 (41.47)
	95% CI of Mean	3.2, 4.0	-15.8, 4.3	3.3, 4.6	-10.8, 16.1
	Median	3.7	-12.0	3.8	0.0
	Q25, Q75	2.6, 4.4	-30.0, 0.0	2.6, 5.6	-17.4, 12.5
	Min, Max	1, 7	-74, 233	1, 7	-81, 164

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Psychological Reward Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 60	n	74	74	36	36
	Missing, n (%)	6 (7.5)	6 (7.5)	5 (12.2)	5 (12.2)
	Mean (SD)	3.5 (1.50)	-10.2 (34.89)	3.7 (1.70)	-7.6 (48.00)
	95% CI of Mean	3.1, 3.9	-18.3, -2.0	3.1, 4.4	-23.9, 8.7
	Median	3.4	-12.3	4.0	-9.6
	Q25, Q75	2.2, 4.4	-31.3, 4.0	2.4, 5.0	-36.1, 5.1
	Min, Max	1, 7	-74, 144	1, 7	-69, 218

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Psychological Reward Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 90	n	73	73	35	35
	Missing, n (%)	7 (8.8)	7 (8.8)	6 (14.6)	6 (14.6)
	Mean (SD)	3.4 (1.47)	-11.8 (36.72)	3.7 (1.68)	-12.1 (28.66)
	95% CI of Mean	3.0, 3.8	-20.4, -3.1	3.1, 4.4	-22.0, -2.2
	Median	3.2	-16.0	3.8	-12.5
	Q25, Q75	2.4, 4.2	-33.3, 0.0	2.6, 4.8	-28.6, 0.0
	Min, Max	1, 7	-76, 117	1, 7	-81, 82

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41	
	Mean (SD)	5.2 (1.32)		5.8 (1.34)	
	95% CI of Mean	4.8, 5.5		5.3, 6.3	
	Median	5.2		6.3	
	Q25, Q75	4.0, 6.3		5.0, 7.0	
	Min, Max	2, 7		2, 7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 1	n	80	80	38	38
	Missing, n (%)	0	0	3 (7.3)	3 (7.3)
	Mean (SD)	3.9 (1.72)	-24.7 (26.85)	5.6 (1.23)	2.7 (40.84)
	95% CI of Mean	3.4, 4.3	-30.7, -18.7	5.2, 6.1	-10.8, 16.1
	Median	4.0	-17.6	5.9	0.0
	Q25, Q75	2.7, 5.0	-41.7, 0.0	4.3, 7.0	-7.0, 0.0
	Min, Max	1, 7	-86, 25	3, 7	-39, 235

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 2	n	80	80	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)
	Mean (SD)	4.3 (1.58)	-15.9 (25.04)	5.6 (1.49)	2.3 (47.45)
	95% CI of Mean	3.9, 4.7	-21.5, -10.2	5.1, 6.1	-13.0, 17.5
	Median	4.2	-8.0	6.0	0.0
	Q25, Q75	3.3, 5.5	-29.1, 0.0	4.5, 7.0	-5.8, 4.7
	Min, Max	1, 7	-86, 30	1, 7	-84, 271

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 3	n	80	80	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)
	Mean (SD)	4.4 (1.57)	-13.7 (26.26)	5.8 (1.24)	6.5 (45.28)
	95% CI of Mean	4.0, 4.7	-19.6, -7.8	5.4, 6.3	-8.1, 21.0
	Median	4.0	-9.3	6.0	0.0
	Q25, Q75	3.3, 5.5	-25.2, 0.0	5.0, 7.0	-4.5, 4.7
	Min, Max	1, 7	-86, 33	3, 7	-42, 271

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 4	n	80	80	40	40
	Missing, n (%)	0	0	1 (2.4)	1 (2.4)
	Mean (SD)	4.4 (1.72)	-14.2 (28.07)	5.7 (1.34)	4.9 (53.13)
	95% CI of Mean	3.9, 4.8	-20.5, -7.9	5.2, 6.2	-12.1, 22.0
	Median	4.0	-7.0	6.0	0.0
	Q25, Q75	3.0, 6.0	-29.9, 0.0	4.9, 7.0	-12.8, 10.8
	Min, Max	1, 7	-86, 58	3, 7	-47, 312

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 5	n	79	79	40	40
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)
	Mean (SD)	4.5 (1.64)	-11.9 (26.42)	5.7 (1.34)	2.5 (31.79)
	95% CI of Mean	4.1, 4.9	-17.9, -6.0	5.2, 6.2	-7.8, 12.7
	Median	4.3	-5.7	6.0	0.0
	Q25, Q75	3.3, 5.7	-20.6, 0.0	4.7, 7.0	-8.8, 9.7
	Min, Max	1, 7	-86, 47	3, 7	-47, 176

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 30	n	76	76	39	39
	Missing, n (%)	4 (5.0)	4 (5.0)	2 (4.9)	2 (4.9)
	Mean (SD)	4.7 (1.42)	-6.6 (26.97)	5.6 (1.39)	-1.1 (15.88)
	95% CI of Mean	4.4, 5.1	-12.8, -0.4	5.1, 6.1	-6.3, 4.1
	Median	5.0	-5.9	6.0	0.0
	Q25, Q75	4.0, 6.0	-20.0, 6.9	4.0, 7.0	-4.3, 6.3
	Min, Max	1, 7	-83, 57	2, 7	-57, 33

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 60	n	74	74	36	36
	Missing, n (%)	6 (7.5)	6 (7.5)	5 (12.2)	5 (12.2)
	Mean (SD)	4.6 (1.46)	-9.4 (26.17)	5.4 (1.46)	-8.4 (20.76)
	95% CI of Mean	4.2, 5.0	-15.5, -3.3	4.8, 5.9	-15.5, -1.3
	Median	4.5	-7.2	5.7	-4.3
	Q25, Q75	3.7, 5.3	-21.7, 5.0	4.2, 6.7	-16.2, 3.0
	Min, Max	1, 7	-86, 62	1, 7	-84, 33

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.54.2 Descriptive Statistics of MCEQ subscales - FAS****Parameter: Smoking Satisfaction Subscale**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)	
		Value	% Change(*)	Value	% Change(*)
Day 90	n	73	73	35	35
	Missing, n (%)	7 (8.8)	7 (8.8)	6 (14.6)	6 (14.6)
	Mean (SD)	4.7 (1.56)	-9.3 (28.48)	5.5 (1.36)	-5.3 (20.44)
	95% CI of Mean	4.2, 5.1	-16.0, -2.6	5.0, 6.0	-12.3, 1.8
	Median	4.3	-7.5	6.0	-4.3
	Q25, Q75	4.0, 6.0	-24.6, 6.4	4.3, 7.0	-14.0, 0.0
	Min, Max	1, 7	-86, 104	3, 7	-43, 73

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.55.1 Analysis of MCEQ Subscales - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Aversion Subscale				
Day 1	n	75	32	
	LS Mean	1.34	1.44	-0.10
	95% CI	1.13, 1.55	1.12, 1.76	-0.47, 0.28
Day 2	n	75	34	
	LS Mean	1.27	1.14	0.12
	95% CI	1.11, 1.42	0.91, 1.37	-0.15, 0.40
Day 3	n	75	34	
	LS Mean	1.23	1.17	0.06
	95% CI	1.09, 1.38	0.96, 1.38	-0.19, 0.31
Day 4	n	75	34	
	LS Mean	1.23	1.17	0.05
	95% CI	1.07, 1.39	0.94, 1.40	-0.22, 0.33

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.1 Analysis of MCEQ Subscales - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Aversion Subscale (cont...)				
Day 5	n	75	34	
	LS Mean	1.33	1.18	0.15
	95% CI	1.13, 1.53	0.89, 1.47	-0.20, 0.49
Day 30	n	39	33	
	LS Mean	1.15	1.21	-0.06
	95% CI	0.97, 1.33	1.02, 1.41	-0.33, 0.20
Day 60	n	39	32	
	LS Mean	1.10	1.19	-0.09
	95% CI	0.92, 1.28	1.00, 1.39	-0.36, 0.17
Day 90	n	47	31	
	LS Mean	1.22	1.14	0.08
	95% CI	1.05, 1.38	0.94, 1.34	-0.18, 0.34

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.1 Analysis of MCEQ Subscales - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Craving Reduction Subscale				
Day 1	n	75	32	
	LS Mean	4.0	5.6	-1.6
	95% CI	3.5, 4.4	4.9, 6.2	-2.3, -0.9
Day 2	n	75	34	
	LS Mean	4.0	5.5	-1.5
	95% CI	3.6, 4.5	4.9, 6.1	-2.2, -0.8
Day 3	n	75	34	
	LS Mean	4.1	5.7	-1.6
	95% CI	3.7, 4.5	5.1, 6.2	-2.3, -0.9
Day 4	n	75	34	
	LS Mean	4.1	5.4	-1.2
	95% CI	3.7, 4.6	4.7, 6.0	-2.0, -0.5

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.1 Analysis of MCEQ Subscales - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Craving Reduction Subscale (cont...)				
Day 5	n	75	34	
	LS Mean	4.3	5.4	-1.1
	95% CI	3.9, 4.7	4.8, 6.0	-1.8, -0.4
Day 30	n	39	32	
	LS Mean	5.1	5.4	-0.4
	95% CI	4.6, 5.6	4.9, 6.0	-1.1, 0.3
Day 60	n	39	32	
	LS Mean	4.8	5.1	-0.3
	95% CI	4.3, 5.3	4.5, 5.7	-1.1, 0.4
Day 90	n	46	31	
	LS Mean	4.6	5.3	-0.7
	95% CI	4.2, 5.0	4.7, 5.8	-1.4, 0.0

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.1 Analysis of MCEQ Subscales - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Enjoyment of Respiratory Tract Sensation Subscale				
Day 1	n	75	32	
	LS Mean	3.4	4.5	-1.1
	95% CI	3.1, 3.8	4.0, 5.1	-1.7, -0.4
Day 2	n	75	34	
	LS Mean	3.7	4.6	-0.8
	95% CI	3.3, 4.1	4.0, 5.1	-1.5, -0.2
Day 3	n	75	34	
	LS Mean	3.6	4.9	-1.3
	95% CI	3.2, 4.0	4.3, 5.4	-1.9, -0.6
Day 4	n	75	34	
	LS Mean	3.8	4.5	-0.7
	95% CI	3.3, 4.3	3.8, 5.1	-1.4, 0.1

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.1 Analysis of MCEQ Subscales - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Enjoyment of Respiratory Tract Sensation Subscale (cont...)				
Day 5	n	75	34	
	LS Mean	3.9	4.6	-0.6
	95% CI	3.5, 4.4	4.0, 5.2	-1.3, 0.1
Day 30	n	39	33	
	LS Mean	4.6	4.9	-0.3
	95% CI	4.1, 5.1	4.4, 5.5	-1.0, 0.4
Day 60	n	39	32	
	LS Mean	4.5	4.8	-0.3
	95% CI	4.0, 5.0	4.3, 5.3	-0.9, 0.4
Day 90	n	47	31	
	LS Mean	4.6	4.7	-0.2
	95% CI	4.1, 5.0	4.2, 5.2	-0.8, 0.5

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.1 Analysis of MCEQ Subscales - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Psychological Reward Subscale				
Day 1	n	75	32	
	LS Mean	3.10	4.01	-0.91
	95% CI	2.84, 3.36	3.61, 4.40	-1.38, -0.45
Day 2	n	75	34	
	LS Mean	3.08	3.73	-0.65
	95% CI	2.84, 3.32	3.38, 4.08	-1.07, -0.23
Day 3	n	75	34	
	LS Mean	3.16	3.63	-0.47
	95% CI	2.91, 3.41	3.27, 4.00	-0.91, -0.04
Day 4	n	75	34	
	LS Mean	3.16	3.65	-0.49
	95% CI	2.90, 3.41	3.27, 4.02	-0.93, -0.04

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.1 Analysis of MCEQ Subscales - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Psychological Reward Subscale (cont...)				
Day 5	n	75	34	
	LS Mean	3.12	3.52	-0.40
	95% CI	2.86, 3.38	3.14, 3.91	-0.86, 0.06
Day 30	n	39	33	
	LS Mean	3.62	4.00	-0.37
	95% CI	3.27, 3.98	3.62, 4.38	-0.89, 0.14
Day 60	n	39	32	
	LS Mean	3.53	3.74	-0.21
	95% CI	3.15, 3.90	3.33, 4.15	-0.76, 0.34
Day 90	n	47	31	
	LS Mean	3.47	3.78	-0.30
	95% CI	3.17, 3.78	3.40, 4.15	-0.78, 0.17

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.1 Analysis of MCEQ Subscales - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Smoking Satisfaction Subscale				
Day 1	n	75	32	
	LS Mean	3.97	5.43	-1.46
	95% CI	3.66, 4.29	4.95, 5.91	-2.03, -0.89
Day 2	n	75	34	
	LS Mean	4.30	5.58	-1.28
	95% CI	3.99, 4.60	5.13, 6.03	-1.82, -0.75
Day 3	n	75	34	
	LS Mean	4.37	5.63	-1.26
	95% CI	4.06, 4.68	5.17, 6.08	-1.81, -0.71
Day 4	n	75	34	
	LS Mean	4.39	5.50	-1.11
	95% CI	4.05, 4.73	4.99, 6.00	-1.71, -0.50

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.1 Analysis of MCEQ Subscales - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Smoking Satisfaction Subscale (cont...)				
Day 5	n	75	34	
	LS Mean	4.54	5.49	-0.96
	95% CI	4.23, 4.84	5.04, 5.94	-1.50, -0.42
Day 30	n	39	33	
	LS Mean	5.11	5.45	-0.34
	95% CI	4.81, 5.41	5.14, 5.77	-0.78, 0.09
Day 60	n	39	32	
	LS Mean	4.93	5.22	-0.28
	95% CI	4.56, 5.31	4.80, 5.63	-0.85, 0.28
Day 90	n	47	31	
	LS Mean	5.01	5.39	-0.37
	95% CI	4.70, 5.33	5.00, 5.77	-0.88, 0.13

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.2 Analysis of MCEQ Subscales - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Aversion Subscale				
Day 1	n	79	38	
	LS Mean	1.33	1.36	-0.03
	95% CI	1.13, 1.53	1.08, 1.64	-0.37, 0.31
Day 2	n	79	40	
	LS Mean	1.25	1.13	0.12
	95% CI	1.11, 1.40	0.93, 1.33	-0.13, 0.37
Day 3	n	79	40	
	LS Mean	1.22	1.16	0.06
	95% CI	1.08, 1.35	0.97, 1.34	-0.16, 0.29
Day 4	n	79	40	
	LS Mean	1.21	1.16	0.06
	95% CI	1.07, 1.36	0.95, 1.36	-0.19, 0.30

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.2 Analysis of MCEQ Subscales - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Aversion Subscale (cont...)				
Day 5	n	78	40	
	LS Mean	1.32	1.17	0.15
	95% CI	1.13, 1.50	0.91, 1.42	-0.16, 0.46
Day 30	n	76	39	
	LS Mean	1.15	1.18	-0.04
	95% CI	1.03, 1.26	1.02, 1.34	-0.23, 0.16
Day 60	n	74	36	
	LS Mean	1.15	1.18	-0.03
	95% CI	1.01, 1.29	0.98, 1.38	-0.27, 0.21
Day 90	n	73	35	
	LS Mean	1.17	1.12	0.05
	95% CI	1.05, 1.30	0.94, 1.30	-0.17, 0.27

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.2 Analysis of MCEQ Subscales - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Craving Reduction Subscale				
Day 1	n	79	38	
	LS Mean	3.9	5.6	-1.7
	95% CI	3.5, 4.4	5.1, 6.2	-2.4, -1.0
Day 2	n	79	40	
	LS Mean	4.2	5.3	-1.0
	95% CI	3.8, 4.6	4.7, 5.8	-1.7, -0.3
Day 3	n	79	40	
	LS Mean	4.2	5.5	-1.3
	95% CI	3.8, 4.6	4.9, 6.1	-2.0, -0.6
Day 4	n	79	40	
	LS Mean	4.2	5.3	-1.0
	95% CI	3.8, 4.7	4.7, 5.9	-1.7, -0.3

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.2 Analysis of MCEQ Subscales - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Craving Reduction Subscale (cont...)				
Day 5	n	78	40	
	LS Mean	4.4	5.3	-0.9
	95% CI	4.0, 4.8	4.8, 5.9	-1.6, -0.3
Day 30	n	76	38	
	LS Mean	4.8	5.6	-0.7
	95% CI	4.4, 5.2	5.0, 6.1	-1.4, -0.1
Day 60	n	74	36	
	LS Mean	4.7	5.2	-0.4
	95% CI	4.3, 5.1	4.6, 5.7	-1.1, 0.3
Day 90	n	72	35	
	LS Mean	4.5	5.3	-0.8
	95% CI	4.2, 4.9	4.8, 5.8	-1.4, -0.2

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.2 Analysis of MCEQ Subscales - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Enjoyment of Respiratory Tract Sensation Subscale				
Day 1	n	79	38	
	LS Mean	3.4	4.4	-1.1
	95% CI	3.0, 3.8	3.9, 5.0	-1.7, -0.4
Day 2	n	79	40	
	LS Mean	3.8	4.4	-0.6
	95% CI	3.4, 4.2	3.8, 4.9	-1.2, 0.1
Day 3	n	79	40	
	LS Mean	3.7	4.8	-1.1
	95% CI	3.3, 4.0	4.3, 5.3	-1.7, -0.5
Day 4	n	79	40	
	LS Mean	3.8	4.4	-0.7
	95% CI	3.3, 4.2	3.8, 5.0	-1.4, 0.1

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.2 Analysis of MCEQ Subscales - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Enjoyment of Respiratory Tract Sensation Subscale (cont...)				
Day 5	n	78	40	
	LS Mean	3.9	4.5	-0.6
	95% CI	3.5, 4.3	4.0, 5.1	-1.3, 0.0
Day 30	n	76	39	
	LS Mean	4.3	4.7	-0.4
	95% CI	3.9, 4.7	4.2, 5.2	-1.1, 0.2
Day 60	n	74	36	
	LS Mean	4.3	4.6	-0.3
	95% CI	3.9, 4.7	4.1, 5.1	-0.9, 0.4
Day 90	n	73	35	
	LS Mean	4.4	4.7	-0.3
	95% CI	4.0, 4.8	4.1, 5.2	-1.0, 0.3

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.2 Analysis of MCEQ Subscales - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Psychological Reward Subscale				
Day 1	n	79	38	
	LS Mean	3.04	3.91	-0.87
	95% CI	2.76, 3.31	3.51, 4.30	-1.34, -0.40
Day 2	n	79	40	
	LS Mean	3.13	3.59	-0.46
	95% CI	2.88, 3.37	3.25, 3.93	-0.88, -0.05
Day 3	n	79	40	
	LS Mean	3.16	3.51	-0.35
	95% CI	2.91, 3.41	3.16, 3.85	-0.77, 0.07
Day 4	n	79	40	
	LS Mean	3.17	3.52	-0.35
	95% CI	2.92, 3.42	3.17, 3.87	-0.78, 0.07

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.2 Analysis of MCEQ Subscales - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Psychological Reward Subscale (cont...)				
Day 5	n	78	40	
	LS Mean	3.13	3.48	-0.35
	95% CI	2.87, 3.40	3.12, 3.85	-0.79, 0.10
Day 30	n	76	39	
	LS Mean	3.56	3.93	-0.37
	95% CI	3.30, 3.82	3.58, 4.29	-0.81, 0.06
Day 60	n	74	36	
	LS Mean	3.51	3.64	-0.13
	95% CI	3.24, 3.78	3.25, 4.03	-0.59, 0.33
Day 90	n	73	35	
	LS Mean	3.43	3.63	-0.20
	95% CI	3.18, 3.69	3.26, 4.00	-0.64, 0.25

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.2 Analysis of MCEQ Subscales - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Smoking Satisfaction Subscale				
Day 1	n	79	38	
	LS Mean	3.98	5.39	-1.41
	95% CI	3.67, 4.30	4.94, 5.84	-1.96, -0.86
Day 2	n	79	40	
	LS Mean	4.41	5.38	-0.97
	95% CI	4.09, 4.72	4.93, 5.82	-1.51, -0.43
Day 3	n	79	40	
	LS Mean	4.48	5.61	-1.13
	95% CI	4.18, 4.77	5.20, 6.02	-1.64, -0.63
Day 4	n	79	40	
	LS Mean	4.48	5.45	-0.97
	95% CI	4.15, 4.81	4.99, 5.91	-1.54, -0.41

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.55.2 Analysis of MCEQ Subscales - FAS**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Smoking Satisfaction Subscale (cont...)				
Day 5	n	78	40	
	LS Mean	4.63	5.45	-0.83
	95% CI	4.33, 4.92	5.04, 5.87	-1.33, -0.32
Day 30	n	76	39	
	LS Mean	4.87	5.42	-0.55
	95% CI	4.60, 5.15	5.04, 5.80	-1.02, -0.08
Day 60	n	74	36	
	LS Mean	4.75	5.16	-0.40
	95% CI	4.45, 5.06	4.71, 5.60	-0.94, 0.14
Day 90	n	73	35	
	LS Mean	4.83	5.32	-0.49
	95% CI	4.52, 5.13	4.87, 5.77	-1.03, 0.05

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.56.1 Descriptive Statistics of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Mean (SD)	0.87 (0.643)		0.77 (0.588)		0.95 (0.743)	
	95% CI of Mean	0.71, 1.02		0.56, 0.97		0.63, 1.27	
	Median	0.67		0.67		0.78	
	Q25, Q75	0.33, 1.33		0.33, 1.00		0.44, 1.11	
	Min, Max	0.0, 3.0		0.0, 2.6		0.1, 3.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.1 Descriptive Statistics of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	0.71 (0.593)	-1.32 (68.172)	0.76 (0.721)	8.27 (70.019)	1.33 (0.945)	86.72 (176.739)
	95% CI of Mean	0.57, 0.85	-17.01, 14.37	0.50, 1.01	-16.16, 32.71	0.93, 1.74	12.09, 161.36
	Median	0.56	-14.29	0.56	0.00	0.94	38.89
	Q25, Q75	0.33, 0.89	-50.00, 16.67	0.33, 1.00	-33.33, 33.33	0.56, 2.06	-19.26, 125.00
	Min, Max	0.0, 3.1	-100.0, 250.0	0.0, 3.2	-100.0, 200.0	0.2, 3.9	-62.5, 800.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.1 Descriptive Statistics of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	0.73 (0.595)	2.70 (82.106)	0.73 (0.688)	8.49 (69.668)	1.23 (0.996)	71.96 (156.058)
	95% CI of Mean	0.59, 0.87	-16.20, 21.59	0.49, 0.98	-15.82, 32.80	0.80, 1.65	6.06, 137.86
	Median	0.56	-16.67	0.56	2.17	0.83	26.67
	Q25, Q75	0.33, 1.00	-50.00, 28.57	0.22, 0.89	-46.67, 33.33	0.44, 2.00	-36.67, 108.33
	Min, Max	0.0, 3.0	-100.0, 500.0	0.0, 2.7	-92.3, 233.3	0.1, 3.3	-80.0, 500.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.1 Descriptive Statistics of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	0.67 (0.587)	-5.85 (98.103)	0.70 (0.623)	-4.18 (57.234)	1.07 (0.921)	42.15 (134.400)
	95% CI of Mean	0.53, 0.81	-28.42, 16.73	0.48, 0.92	-24.15, 15.79	0.68, 1.46	-14.61, 98.91
	Median	0.67	-30.00	0.50	-3.85	0.72	-11.11
	Q25, Q75	0.22, 1.00	-57.14, 8.33	0.33, 0.78	-44.44, 33.33	0.33, 2.17	-45.00, 111.11
	Min, Max	0.0, 3.0	-100.0, 550.0	0.0, 2.6	-100.0, 155.6	0.0, 2.6	-100.0, 475.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.1 Descriptive Statistics of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	75	75	34	34	24	24
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	0.68 (0.586)	-5.13 (93.345)	0.69 (0.684)	4.53 (73.869)	0.92 (0.807)	20.36 (128.843)
	95% CI of Mean	0.54, 0.82	-26.61, 16.36	0.44, 0.93	-21.25, 30.31	0.57, 1.26	-34.05, 74.77
	Median	0.56	-25.00	0.44	-6.25	0.50	-30.30
	Q25, Q75	0.22, 1.00	-50.00, 9.09	0.33, 0.78	-50.00, 33.33	0.33, 1.61	-54.17, 78.33
	Min, Max	0.0, 3.0	-100.0, 600.0	0.0, 2.8	-100.0, 214.3	0.0, 2.7	-100.0, 500.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.1 Descriptive Statistics of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day	n	75	75	34	34	24	24
6/Discharge							
Confinement							
	Missing, n(%)	0	0	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	0.68 (0.618)	-0.52 (104.286)	0.76 (0.702)	1.58 (66.551)	0.86 (0.768)	7.68 (90.901)
	95% CI of Mean	0.54, 0.83	-24.52, 23.47	0.52, 1.01	-21.64, 24.81	0.53, 1.19	-30.71, 46.07
	Median	0.56	-25.00	0.56	0.00	0.67	0.00
	Q25, Q75	0.22, 1.11	-56.25, 13.33	0.33, 1.00	-40.00, 33.33	0.22, 1.56	-59.72, 38.33
	Min, Max	0.0, 3.0	-100.0, 500.0	0.0, 2.8	-100.0, 228.6	0.0, 2.3	-100.0, 300.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.1 Descriptive Statistics of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	40		34		13	
	Mean (SD)	0.87 (0.720)		0.75 (0.590)		1.16 (0.906)	
	95% CI of Mean	0.63, 1.10		0.54, 0.97		0.61, 1.71	
	Median	0.67		0.67		1.00	
	Q25, Q75	0.28, 1.33		0.33, 1.00		0.56, 1.22	
	Min, Max	0.0, 3.0		0.0, 2.6		0.2, 3.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.1 Descriptive Statistics of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	39	39	33	33	13	13
	Missing, n(%)	1 (2.5)	1 (2.5)	1 (2.9)	1 (2.9)	0	0
	Mean (SD)	0.47 (0.440)	-22.10 (77.280)	0.57 (0.577)	-11.79 (57.218)	0.71 (0.806)	-15.02 (110.127)
	95% CI of Mean	0.32, 0.62	-47.16, 2.96	0.36, 0.78	-32.08, 8.50	0.22, 1.20	-81.58, 51.53
	Median	0.33	-45.45	0.33	0.00	0.33	-55.56
	Q25, Q75	0.22, 0.67	-83.33, 25.00	0.22, 0.78	-62.50, 33.33	0.11, 1.33	-92.59, 40.00
	Min, Max	0.0, 2.1	-100.0, 225.0	0.0, 2.1	-100.0, 111.1	0.0, 2.6	-100.0, 250.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.1 Descriptive Statistics of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	39		35		12	
	Mean (SD)	0.88 (0.741)		0.78 (0.606)		1.28 (0.900)	
	95% CI of Mean	0.64, 1.13		0.57, 1.00		0.70, 1.85	
	Median	0.67		0.67		1.11	
	Q25, Q75	0.22, 1.33		0.33, 1.00		0.72, 1.44	
	Min, Max	0.0, 3.0		0.0, 2.6		0.2, 3.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.1 Descriptive Statistics of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	39	39	32	32	11	11
	Missing, n(%)	0	0	3 (8.6)	3 (8.6)	1 (8.3)	1 (8.3)
	Mean (SD)	0.50 (0.468)	-21.82 (59.472)	0.55 (0.633)	-26.00 (50.793)	0.47 (0.459)	-56.26 (36.921)
	95% CI of Mean	0.34, 0.65	-41.11, -2.54	0.32, 0.78	-44.32, -7.68	0.16, 0.79	-81.07, -31.45
	Median	0.44	-16.67	0.33	-33.33	0.22	-62.96
	Q25, Q75	0.22, 0.67	-66.67, 0.00	0.22, 0.61	-63.07, 0.00	0.11, 1.11	-92.59, -30.00
	Min, Max	0.0, 1.8	-100.0, 166.7	0.0, 3.1	-100.0, 100.0	0.0, 1.1	-100.0, 0.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.1 Descriptive Statistics of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	0.89 (0.725)		0.85 (0.594)		1.12 (0.842)	
	95% CI of Mean	0.67, 1.11		0.63, 1.07		0.47, 1.78	
	Median	0.67		0.72		1.00	
	Q25, Q75	0.22, 1.44		0.39, 1.11		0.56, 1.22	
	Min, Max	0.0, 3.0		0.0, 2.6		0.2, 3.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.1 Descriptive Statistics of MNWS Total Scores - PP Set****Parameter: MNWS-R withdrawal score****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	31	31	9	9
	Missing, n(%)	0	0	1 (3.1)	1 (3.1)	0	0
	Mean (SD)	0.51 (0.481)	-16.04 (75.627)	0.57 (0.495)	-16.98 (54.222)	0.38 (0.539)	-53.24 (72.245)
	95% CI of Mean	0.36, 0.65	-38.25, 6.17	0.39, 0.76	-36.87, 2.92	-0.04, 0.80	-108.78, 2.29
	Median	0.33	-40.00	0.44	-25.00	0.33	-88.89
	Q25, Q75	0.22, 0.78	-71.43, 33.33	0.22, 0.67	-66.67, 28.57	0.00, 0.44	-100.00, -60.00
	Min, Max	0.0, 1.9	-100.0, 250.0	0.0, 2.3	-100.0, 100.0	0.0, 1.7	-100.0, 100.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.2 Descriptive Statistics of MNWS Total Scores - FAS****Parameter: MNWS-R withdrawal score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	80		41		39	
	Mean (SD)	0.87 (0.644)		0.85 (0.658)		0.87 (0.686)	
	95% CI of Mean	0.72, 1.02		0.64, 1.06		0.64, 1.10	
	Median	0.67		0.67		0.67	
	Q25, Q75	0.39, 1.33		0.33, 1.11		0.33, 1.22	
	Min, Max	0.0, 3.0		0.0, 2.8		0.1, 3.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.2 Descriptive Statistics of MNWS Total Scores - FAS****Parameter: MNWS-R withdrawal score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 2	n	80	79	40	40	34	34
	Missing, n(%)	0	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
	Mean (SD)	0.73 (0.593)	8.10 (112.340)	0.73 (0.683)	1.89 (69.400)	1.14 (0.878)	71.00 (158.454)
	95% CI of Mean	0.59, 0.86	-17.06, 33.27	0.50, 0.95	-20.31, 24.09	0.83, 1.45	15.71, 126.29
	Median	0.56	-13.33	0.56	0.00	0.89	27.31
	Q25, Q75	0.33, 0.89	-50.00, 16.67	0.28, 1.00	-48.33, 30.95	0.44, 1.67	-20.00, 100.00
	Min, Max	0.0, 3.1	-100.0, 800.0	0.0, 3.2	-100.0, 200.0	0.1, 3.9	-62.5, 800.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.2 Descriptive Statistics of MNWS Total Scores - FAS****Parameter: MNWS-R withdrawal score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 3	n	80	79	40	40	34	34
	Missing, n(%)	0	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
	Mean (SD)	0.74 (0.592)	9.43 (104.948)	0.70 (0.648)	1.18 (69.981)	1.05 (0.920)	62.29 (159.390)
	95% CI of Mean	0.60, 0.88	-14.08, 32.95	0.49, 0.91	-21.21, 23.56	0.72, 1.37	6.68, 117.91
	Median	0.61	-14.29	0.56	0.00	0.67	8.25
	Q25, Q75	0.33, 1.00	-50.00, 28.57	0.28, 0.89	-55.40, 33.33	0.33, 1.44	-40.00, 100.00
	Min, Max	0.0, 3.0	-100.0, 600.0	0.0, 2.7	-92.3, 233.3	0.1, 3.3	-80.0, 500.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.2 Descriptive Statistics of MNWS Total Scores - FAS****Parameter: MNWS-R withdrawal score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	80	79	40	40	34	34
	Missing, n(%)	0	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
	Mean (SD)	0.66 (0.575)	-3.65 (102.295)	0.67 (0.589)	-9.35 (59.781)	0.92 (0.840)	37.82 (136.601)
	95% CI of Mean	0.53, 0.79	-26.57, 19.26	0.47, 0.86	-28.48, 9.77	0.62, 1.22	-9.85, 85.49
	Median	0.67	-30.00	0.50	-13.19	0.67	-19.44
	Q25, Q75	0.22, 1.00	-57.14, 8.33	0.33, 0.78	-50.00, 30.95	0.22, 1.33	-50.00, 100.00
	Min, Max	0.0, 3.0	-100.0, 550.0	0.0, 2.6	-100.0, 155.6	0.0, 2.6	-100.0, 475.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.2 Descriptive Statistics of MNWS Total Scores - FAS****Parameter: MNWS-R withdrawal score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	79	79	40	40	34	34
	Missing, n(%)	1 (1.3)	1 (1.3)	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
	Mean (SD)	0.69 (0.585)	-1.91 (97.399)	0.67 (0.635)	-0.99 (71.953)	0.81 (0.736)	25.29 (140.559)
	95% CI of Mean	0.56, 0.83	-23.73, 19.91	0.46, 0.88	-24.01, 22.02	0.55, 1.07	-23.76, 74.34
	Median	0.56	-20.00	0.44	-13.39	0.50	-27.27
	Q25, Q75	0.33, 1.00	-50.00, 9.09	0.33, 0.72	-53.94, 33.33	0.22, 1.22	-62.96, 90.00
	Min, Max	0.0, 3.0	-100.0, 600.0	0.0, 2.8	-100.0, 214.3	0.0, 2.7	-100.0, 500.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.2 Descriptive Statistics of MNWS Total Scores - FAS****Parameter: MNWS-R withdrawal score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day	n	80	80	40	40	34	34
6/Discharge							
Confinement							
	Missing, n(%)	0	0	1 (2.4)	1 (2.4)	5 (12.8)	5 (12.8)
	Mean (SD)	0.69 (0.612)	-0.65 (101.170)	0.73 (0.666)	-2.79 (67.093)	0.74 (0.718)	7.81 (115.345)
	95% CI of Mean	0.55, 0.83	-23.17, 21.87	0.51, 0.95	-24.25, 18.68	0.49, 1.00	-32.44, 48.06
	Median	0.56	-22.50	0.56	-10.00	0.44	-17.05
	Q25, Q75	0.22, 1.06	-53.24, 12.92	0.33, 0.94	-40.00, 26.67	0.11, 1.22	-80.00, 26.67
	Min, Max	0.0, 3.0	-100.0, 500.0	0.0, 2.8	-100.0, 228.6	0.0, 2.3	-100.0, 450.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.2 Descriptive Statistics of MNWS Total Scores - FAS****Parameter: MNWS-R withdrawal score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	76	76	39	39	33	33
	Missing, n(%)	4 (5.0)	4 (5.0)	2 (4.9)	2 (4.9)	6 (15.4)	6 (15.4)
	Mean (SD)	0.61 (0.544)	-4.57 (99.024)	0.56 (0.544)	-17.39 (57.085)	0.61 (0.637)	-8.28 (109.406)
	95% CI of Mean	0.48, 0.74	-27.21, 18.06	0.37, 0.74	-35.90, 1.12	0.38, 0.84	-47.07, 30.52
	Median	0.44	-35.42	0.33	-17.39	0.33	-46.67
	Q25, Q75	0.22, 0.78	-69.62, 33.33	0.22, 0.78	-66.67, 33.33	0.11, 0.89	-75.00, 0.00
	Min, Max	0.0, 2.3	-100.0, 350.0	0.0, 2.1	-100.0, 111.1	0.0, 2.6	-100.0, 350.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.2 Descriptive Statistics of MNWS Total Scores - FAS****Parameter: MNWS-R withdrawal score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	72	72	36	36	30	30
	Missing, n(%)	8 (10.0)	8 (10.0)	5 (12.2)	5 (12.2)	9 (23.1)	9 (23.1)
	Mean (SD)	0.52 (0.518)	-14.67 (86.550)	0.56 (0.607)	-28.32 (49.125)	0.34 (0.334)	-49.09 (54.465)
	95% CI of Mean	0.40, 0.65	-35.02, 5.67	0.35, 0.77	-44.95, -11.70	0.21, 0.47	-69.43, -28.75
	Median	0.44	-28.99	0.33	-34.52	0.22	-66.67
	Q25, Q75	0.11, 0.67	-82.14, 3.33	0.22, 0.67	-63.07, 0.00	0.11, 0.44	-88.89, -33.33
	Min, Max	0.0, 2.7	-100.0, 400.0	0.0, 3.1	-100.0, 100.0	0.0, 1.1	-100.0, 150.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.56.2 Descriptive Statistics of MNWS Total Scores - FAS****Parameter: MNWS-R withdrawal score**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	73	73	35	35	31	31
	Missing, n(%)	7 (8.8)	7 (8.8)	6 (14.6)	6 (14.6)	8 (20.5)	8 (20.5)
	Mean (SD)	0.60 (0.539)	-1.46 (105.654)	0.52 (0.492)	-25.74 (56.667)	0.46 (0.457)	-25.92 (95.212)
	95% CI of Mean	0.47, 0.73	-26.11, 23.20	0.34, 0.69	-45.21, -6.26	0.28, 0.63	-60.85, 9.01
	Median	0.44	-25.00	0.44	-33.33	0.33	-60.00
	Q25, Q75	0.22, 0.78	-68.75, 22.22	0.13, 0.67	-73.33, 22.22	0.11, 0.67	-88.89, 0.00
	Min, Max	0.0, 2.1	-100.0, 400.0	0.0, 2.3	-100.0, 100.0	0.0, 1.7	-100.0, 300.0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.57.1 Analysis of MNWS Total Scores - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
MNWS-R withdrawal score						
Day 2	n	75	34	24		
	LS Mean	0.71	0.83	1.28	-0.12	-0.57
	95% CI	0.59, 0.84	0.65, 1.02	1.06, 1.50	-0.34, 0.10	-0.82, -0.32
Day 3	n	75	34	24		
	LS Mean	0.73	0.79	1.18	-0.06	-0.45
	95% CI	0.59, 0.87	0.59, 1.00	0.94, 1.42	-0.31, 0.18	-0.73, -0.18
Day 4	n	75	34	24		
	LS Mean	0.65	0.75	1.01	-0.09	-0.36
	95% CI	0.52, 0.79	0.55, 0.94	0.78, 1.24	-0.32, 0.14	-0.62, -0.10
Day 5	n	75	34	24		
	LS Mean	0.68	0.74	0.87	-0.06	-0.19
	95% CI	0.55, 0.81	0.54, 0.93	0.64, 1.10	-0.29, 0.17	-0.45, 0.07

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.57.1 Analysis of MNWS Total Scores - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
MNWS-R withdrawal score (cont...)						
Day 6/Discharge Confinement	n	75	34	24		
	LS Mean	0.67	0.82	0.79	-0.15	-0.12
	95% CI	0.54, 0.80	0.63, 1.00	0.56, 1.01	-0.37, 0.08	-0.37, 0.13
Day 30	n	39	33	13		
	LS Mean	0.48	0.61	0.64	-0.13	-0.16
	95% CI	0.30, 0.66	0.42, 0.81	0.34, 0.95	-0.39, 0.13	-0.51, 0.19
Day 60	n	39	32	11		
	LS Mean	0.49	0.58	0.34	-0.09	0.15
	95% CI	0.33, 0.65	0.40, 0.76	0.03, 0.65	-0.33, 0.15	-0.19, 0.50
Day 90	n	47	31	9		
	LS Mean	0.51	0.59	0.34	-0.08	0.17
	95% CI	0.36, 0.66	0.41, 0.77	0.00, 0.67	-0.31, 0.15	-0.19, 0.53

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.57.2 Analysis of MNWS Total Scores - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
MNWS-R withdrawal score						
Day 2	n	79	40	34		
	LS Mean	0.73	0.75	1.18	-0.02	-0.44
	95% CI	0.60, 0.86	0.58, 0.93	0.98, 1.37	-0.24, 0.19	-0.67, -0.22
Day 3	n	79	40	34		
	LS Mean	0.74	0.72	1.08	0.02	-0.34
	95% CI	0.61, 0.88	0.54, 0.91	0.88, 1.28	-0.21, 0.25	-0.58, -0.10
Day 4	n	79	40	34		
	LS Mean	0.65	0.68	0.94	-0.03	-0.29
	95% CI	0.52, 0.78	0.50, 0.85	0.75, 1.13	-0.24, 0.19	-0.51, -0.06
Day 5	n	79	40	34		
	LS Mean	0.70	0.69	0.83	0.00	-0.14
	95% CI	0.57, 0.82	0.52, 0.87	0.65, 1.02	-0.21, 0.21	-0.36, 0.08

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.57.2 Analysis of MNWS Total Scores - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
MNWS-R withdrawal score (cont...)						
Day 6/Discharge Confinement	n	79	40	34		
	LS Mean	0.68	0.74	0.75	-0.06	-0.07
	95% CI	0.55, 0.81	0.56, 0.91	0.56, 0.94	-0.27, 0.16	-0.30, 0.15
Day 30	n	76	39	33		
	LS Mean	0.61	0.58	0.62	0.03	0.00
	95% CI	0.49, 0.74	0.40, 0.75	0.43, 0.81	-0.18, 0.25	-0.23, 0.22
Day 60	n	72	36	30		
	LS Mean	0.52	0.54	0.34	-0.02	0.18
	95% CI	0.40, 0.64	0.38, 0.70	0.16, 0.51	-0.22, 0.17	-0.03, 0.39
Day 90	n	73	35	31		
	LS Mean	0.60	0.52	0.46	0.09	0.14
	95% CI	0.48, 0.72	0.35, 0.69	0.28, 0.64	-0.12, 0.29	-0.07, 0.35

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking different
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	73	34	23
	Missing, n(%)	2 (2.7)	1 (2.9)	1 (4.2)
	Mean (SD)	3.48 (1.226)	3.68 (1.094)	3.48 (1.202)
	95% CI of Mean	3.19, 3.77	3.29, 4.06	2.95, 4.00
	Median	4.00	4.00	4.00
	Q25, Q75	3.00, 4.00	3.00, 4.00	2.00, 4.00
	Min, Max	1.0, 5.0	1.0, 5.0	1.0, 5.0
Day 4	n	75	33	
	Missing, n(%)	0	2 (5.7)	
	Mean (SD)	3.92 (1.148)	3.58 (1.147)	
	95% CI of Mean	3.65, 4.19	3.16, 3.99	
	Median	4.00	4.00	
	Q25, Q75	3.00, 5.00	3.00, 4.00	
	Min, Max	1.0, 5.0	1.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.
Appendix 15.3.7.1

**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking different
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	39	33	13
	Missing, n(%)	1 (2.5)	1 (2.9)	0
	Mean (SD)	3.26 (1.272)	3.64 (1.085)	3.54 (1.127)
	95% CI of Mean	2.84, 3.67	3.25, 4.03	2.85, 4.22
	Median	4.00	4.00	4.00
	Q25, Q75	2.00, 4.00	3.00, 4.00	3.00, 4.00
	Min, Max	1.0, 5.0	1.0, 5.0	2.0, 5.0
Day 30	n	39	29	
	Missing, n(%)	1 (2.5)	5 (14.7)	
	Mean (SD)	3.38 (1.139)	3.14 (1.157)	
	95% CI of Mean	3.01, 3.76	2.69, 3.58	
	Median	4.00	3.00	
	Q25, Q75	3.00, 4.00	3.00, 4.00	
	Min, Max	1.0, 5.0	1.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.
Appendix 15.3.7.1

**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking different
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	38	34	12
	Missing, n(%)	1 (2.6)	1 (2.9)	0
	Mean (SD)	3.21 (1.190)	3.65 (1.070)	3.50 (1.000)
	95% CI of Mean	2.81, 3.61	3.27, 4.03	2.86, 4.14
	Median	3.00	4.00	3.50
	Q25, Q75	3.00, 4.00	3.00, 4.00	3.00, 4.00
	Min, Max	1.0, 5.0	1.0, 5.0	2.0, 5.0
Day 60	n	39	32	
	Missing, n(%)	0	3 (8.6)	
	Mean (SD)	3.31 (1.174)	3.25 (1.108)	
	95% CI of Mean	2.92, 3.69	2.85, 3.65	
	Median	3.00	3.00	
	Q25, Q75	3.00, 4.00	3.00, 4.00	
	Min, Max	1.0, 5.0	1.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.
Appendix 15.3.7.1

**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking different
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	46	31	9
	Missing, n(%)	1 (2.1)	1 (3.1)	0
	Mean (SD)	3.28 (1.224)	3.58 (1.089)	3.56 (0.882)
	95% CI of Mean	2.91, 3.65	3.18, 3.98	2.87, 4.24
	Median	4.00	4.00	4.00
	Q25, Q75	3.00, 4.00	3.00, 4.00	3.00, 4.00
	Min, Max	1.0, 5.0	1.0, 5.0	2.0, 5.0
Day 90	n	45	24	
	Missing, n(%)	2 (4.3)	8 (25.0)	
	Mean (SD)	3.24 (1.132)	3.04 (1.161)	
	95% CI of Mean	2.90, 3.59	2.55, 3.54	
	Median	3.00	3.00	
	Q25, Q75	3.00, 4.00	2.50, 4.00	
	Min, Max	1.0, 5.0	1.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.
Appendix 15.3.7.1

**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Enjoy smoking
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	73	34	23
	Missing, n(%)	2 (2.7)	1 (2.9)	1 (4.2)
	Mean (SD)	2.75 (1.165)	2.76 (1.130)	3.17 (1.030)
	95% CI of Mean	2.48, 3.03	2.37, 3.16	2.72, 3.62
	Median	3.00	3.00	3.00
	Q25, Q75	2.00, 3.00	2.00, 3.00	2.00, 4.00
	Min, Max	1.0, 5.0	1.0, 5.0	1.0, 5.0
Day 4	n	75	33	
	Missing, n(%)	0	2 (5.7)	
	Mean (SD)	2.75 (1.164)	2.70 (1.132)	
	95% CI of Mean	2.47, 3.02	2.29, 3.10	
	Median	3.00	3.00	
	Q25, Q75	2.00, 3.00	2.00, 3.00	
	Min, Max	1.0, 5.0	1.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.
Appendix 15.3.7.1

**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Enjoy smoking
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	39	33	13
	Missing, n(%)	1 (2.5)	1 (2.9)	0
	Mean (SD)	2.95 (1.213)	2.79 (1.140)	2.92 (1.321)
	95% CI of Mean	2.55, 3.35	2.38, 3.20	2.12, 3.73
	Median	3.00	3.00	3.00
	Q25, Q75	2.00, 4.00	2.00, 3.00	2.00, 4.00
	Min, Max	1.0, 5.0	1.0, 5.0	1.0, 5.0
Day 30	n	39	29	
	Missing, n(%)	1 (2.5)	5 (14.7)	
	Mean (SD)	3.41 (0.939)	3.21 (1.082)	
	95% CI of Mean	3.10, 3.72	2.79, 3.62	
	Median	3.00	3.00	
	Q25, Q75	3.00, 4.00	3.00, 4.00	
	Min, Max	1.0, 5.0	1.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.
Appendix 15.3.7.1

**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Enjoy smoking****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	38	34	12
	Missing, n(%)	1 (2.6)	1 (2.9)	0
	Mean (SD)	2.87 (1.167)	2.74 (1.163)	3.00 (1.478)
	95% CI of Mean	2.48, 3.26	2.32, 3.15	2.06, 3.94
	Median	3.00	3.00	3.00
	Q25, Q75	2.00, 4.00	2.00, 3.00	1.50, 4.00
	Min, Max	1.0, 5.0	1.0, 5.0	1.0, 5.0
Day 60	n	39	32	
	Missing, n(%)	0	3 (8.6)	
	Mean (SD)	3.23 (1.038)	2.78 (1.070)	
	95% CI of Mean	2.89, 3.57	2.39, 3.17	
	Median	3.00	3.00	
	Q25, Q75	3.00, 4.00	2.00, 3.00	
	Min, Max	1.0, 5.0	1.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Enjoy smoking
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	46	31	9
	Missing, n(%)	1 (2.1)	1 (3.1)	0
	Mean (SD)	2.80 (1.186)	2.71 (1.102)	2.89 (1.365)
	95% CI of Mean	2.45, 3.16	2.30, 3.12	1.84, 3.94
	Median	3.00	3.00	3.00
	Q25, Q75	2.00, 3.00	2.00, 3.00	2.00, 4.00
	Min, Max	1.0, 5.0	1.0, 5.0	1.0, 5.0
Day 90	n	45	24	
	Missing, n(%)	2 (4.3)	8 (25.0)	
	Mean (SD)	3.16 (0.976)	3.25 (1.152)	
	95% CI of Mean	2.86, 3.45	2.76, 3.74	
	Median	3.00	3.00	
	Q25, Q75	3.00, 3.00	3.00, 4.00	
	Min, Max	1.0, 5.0	1.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking Taste****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	73	33	23
	Missing, n(%)	2 (2.7)	2 (5.7)	1 (4.2)
	Mean (SD)	2.82 (1.206)	2.73 (1.098)	2.83 (1.267)
	95% CI of Mean	2.54, 3.11	2.33, 3.12	2.27, 3.38
	Median	3.00	3.00	2.00
	Q25, Q75	2.00, 4.00	2.00, 3.00	2.00, 4.00
	Min, Max	1.0, 5.0	1.0, 5.0	1.0, 5.0
Day 4	n	75	33	
	Missing, n(%)	0	2 (5.7)	
	Mean (SD)	3.43 (1.233)	2.94 (1.249)	
	95% CI of Mean	3.14, 3.72	2.49, 3.39	
	Median	4.00	3.00	
	Q25, Q75	3.00, 4.00	2.00, 4.00	
	Min, Max	1.0, 5.0	1.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking Taste
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	39	32	12
	Missing, n(%)	1 (2.5)	2 (5.9)	1 (7.7)
	Mean (SD)	2.77 (1.267)	2.75 (1.164)	3.25 (1.216)
	95% CI of Mean	2.35, 3.18	2.33, 3.17	2.47, 4.03
	Median	3.00	3.00	3.50
	Q25, Q75	2.00, 4.00	2.00, 3.00	2.00, 4.00
	Min, Max	1.0, 5.0	1.0, 5.0	2.0, 5.0
Day 30	n	39	28	
	Missing, n(%)	1 (2.5)	6 (17.6)	
	Mean (SD)	2.95 (1.213)	2.82 (1.157)	
	95% CI of Mean	2.55, 3.35	2.37, 3.27	
	Median	3.00	3.00	
	Q25, Q75	2.00, 4.00	2.00, 4.00	
	Min, Max	1.0, 5.0	1.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.
Appendix 15.3.7.1

**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking Taste****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	38	33	11
	Missing, n(%)	1 (2.6)	2 (5.7)	1 (8.3)
	Mean (SD)	2.58 (1.178)	2.79 (1.167)	3.09 (1.376)
	95% CI of Mean	2.19, 2.97	2.37, 3.21	2.16, 4.02
	Median	2.50	3.00	3.00
	Q25, Q75	2.00, 3.00	2.00, 3.00	2.00, 4.00
	Min, Max	1.0, 5.0	1.0, 5.0	1.0, 5.0
Day 60	n	38	30	
	Missing, n(%)	1 (2.6)	5 (14.3)	
	Mean (SD)	2.82 (1.062)	2.90 (1.094)	
	95% CI of Mean	2.46, 3.17	2.49, 3.31	
	Median	3.00	3.00	
	Q25, Q75	2.00, 3.00	2.00, 3.00	
	Min, Max	1.0, 5.0	1.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Smoking Taste****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	46	30	8
	Missing, n(%)	1 (2.1)	2 (6.3)	1 (11.1)
	Mean (SD)	2.70 (1.209)	2.73 (1.202)	3.25 (1.165)
	95% CI of Mean	2.33, 3.06	2.28, 3.19	2.27, 4.23
	Median	3.00	3.00	3.50
	Q25, Q75	2.00, 4.00	2.00, 3.00	2.00, 4.00
	Min, Max	1.0, 5.0	1.0, 5.0	2.0, 5.0
Day 90	n	44	22	
	Missing, n(%)	3 (6.4)	10 (31.3)	
	Mean (SD)	2.84 (1.078)	2.50 (0.802)	
	95% CI of Mean	2.51, 3.17	2.14, 2.86	
	Median	3.00	2.50	
	Q25, Q75	2.00, 3.00	2.00, 3.00	
	Min, Max	1.0, 5.0	1.0, 4.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Easy to use****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	73	33	23
	Missing, n(%)	2 (2.7)	2 (5.7)	1 (4.2)
	Mean (SD)	4.15 (0.938)	4.21 (0.820)	4.35 (0.776)
	95% CI of Mean	3.93, 4.37	3.92, 4.51	4.01, 4.69
	Median	4.00	4.00	5.00
	Q25, Q75	4.00, 5.00	4.00, 5.00	4.00, 5.00
	Min, Max	1.0, 5.0	2.0, 5.0	3.0, 5.0
Day 4	n	75	33	
	Missing, n(%)	0	2 (5.7)	
	Mean (SD)	3.52 (1.108)	4.06 (0.934)	
	95% CI of Mean	3.26, 3.78	3.72, 4.40	
	Median	4.00	4.00	
	Q25, Q75	3.00, 4.00	3.00, 5.00	
	Min, Max	1.0, 5.0	2.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Easy to use****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	39	32	12
	Missing, n(%)	1 (2.5)	2 (5.9)	1 (7.7)
	Mean (SD)	4.18 (0.970)	4.22 (0.833)	4.25 (0.754)
	95% CI of Mean	3.86, 4.50	3.91, 4.52	3.77, 4.73
	Median	4.00	4.00	4.00
	Q25, Q75	4.00, 5.00	4.00, 5.00	4.00, 5.00
	Min, Max	1.0, 5.0	2.0, 5.0	3.0, 5.0
Day 30	n	39	28	
	Missing, n(%)	1 (2.5)	6 (17.6)	
	Mean (SD)	3.90 (0.941)	3.89 (0.686)	
	95% CI of Mean	3.59, 4.21	3.62, 4.16	
	Median	4.00	4.00	
	Q25, Q75	3.00, 5.00	3.00, 4.00	
	Min, Max	1.0, 5.0	3.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Easy to use****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	38	33	11
	Missing, n(%)	1 (2.6)	2 (5.7)	1 (8.3)
	Mean (SD)	4.13 (1.018)	4.24 (0.831)	4.09 (0.832)
	95% CI of Mean	3.79, 4.47	3.94, 4.54	3.53, 4.65
	Median	4.00	4.00	4.00
	Q25, Q75	4.00, 5.00	4.00, 5.00	3.00, 5.00
	Min, Max	1.0, 5.0	2.0, 5.0	3.0, 5.0
Day 60	n	38	31	
	Missing, n(%)	1 (2.6)	4 (11.4)	
	Mean (SD)	3.79 (0.964)	4.03 (0.875)	
	95% CI of Mean	3.47, 4.11	3.71, 4.36	
	Median	4.00	4.00	
	Q25, Q75	3.00, 5.00	3.00, 5.00	
	Min, Max	1.0, 5.0	2.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set****Parameter: Easy to use****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	46	30	8
	Missing, n(%)	1 (2.1)	2 (6.3)	1 (11.1)
	Mean (SD)	4.15 (0.943)	4.30 (0.750)	3.75 (0.708)
	95% CI of Mean	3.87, 4.44	4.02, 4.58	3.15, 4.35
	Median	4.00	4.00	4.00
	Q25, Q75	4.00, 5.00	4.00, 5.00	3.00, 4.00
	Min, Max	1.0, 5.0	2.0, 5.0	3.0, 5.0
Day 90	n	44	22	
	Missing, n(%)	3 (6.4)	10 (31.3)	
	Mean (SD)	3.70 (1.091)	4.09 (0.812)	
	95% CI of Mean	3.37, 4.04	3.73, 4.46	
	Median	4.00	4.00	
	Q25, Q75	3.00, 5.00	3.00, 5.00	
	Min, Max	1.0, 5.0	3.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking disturbed
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	73	33	23
	Missing, n(%)	2 (2.7)	2 (5.7)	1 (4.2)
	Mean (SD)	2.84 (1.143)	2.97 (1.132)	2.74 (1.137)
	95% CI of Mean	2.56, 3.11	2.56, 3.38	2.24, 3.24
	Median	3.00	3.00	3.00
	Q25, Q75	2.00, 4.00	2.00, 3.00	2.00, 4.00
	Min, Max	1.0, 5.0	1.0, 5.0	1.0, 5.0
Day 4	n	75	33	
	Missing, n(%)	0	2 (5.7)	
	Mean (SD)	3.13 (1.083)	3.03 (1.046)	
	95% CI of Mean	2.88, 3.39	2.65, 3.41	
	Median	3.00	3.00	
	Q25, Q75	3.00, 4.00	2.00, 3.00	
	Min, Max	1.0, 5.0	1.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.
Appendix 15.3.7.1

**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking disturbed
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)	mCC (N=34)	SA (N=13)
		Value	Value	Value
Baseline	n	39	32	12
	Missing, n(%)	1 (2.5)	2 (5.9)	1 (7.7)
	Mean (SD)	2.74 (1.333)	2.94 (1.135)	2.83 (1.268)
	95% CI of Mean	2.31, 3.18	2.52, 3.35	2.02, 3.64
	Median	3.00	3.00	2.50
	Q25, Q75	2.00, 4.00	2.00, 3.00	2.00, 3.50
	Min, Max	1.0, 5.0	1.0, 5.0	1.0, 5.0
Day 30	n	39	28	
	Missing, n(%)	1 (2.5)	6 (17.6)	
	Mean (SD)	2.49 (0.943)	2.75 (1.076)	
	95% CI of Mean	2.18, 2.80	2.33, 3.17	
	Median	3.00	3.00	
	Q25, Q75	2.00, 3.00	2.00, 3.00	
	Min, Max	1.0, 5.0	1.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking disturbed
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)	mCC (N=35)	SA (N=12)
		Value	Value	Value
Baseline	n	38	33	11
	Missing, n(%)	1 (2.6)	2 (5.7)	1 (8.3)
	Mean (SD)	2.71 (1.229)	3.00 (1.173)	2.91 (1.301)
	95% CI of Mean	2.30, 3.12	2.58, 3.42	2.03, 3.79
	Median	3.00	3.00	3.00
	Q25, Q75	2.00, 3.00	2.00, 3.00	2.00, 4.00
	Min, Max	1.0, 5.0	1.0, 5.0	1.0, 5.0
Day 60	n	38	31	
	Missing, n(%)	1 (2.6)	4 (11.4)	
	Mean (SD)	2.66 (0.848)	3.03 (1.017)	
	95% CI of Mean	2.37, 2.94	2.65, 3.41	
	Median	3.00	3.00	
	Q25, Q75	2.00, 3.00	3.00, 3.00	
	Min, Max	1.0, 4.0	1.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.58 Descriptive Statistics of HST Questionnaire Data - PP Set**

Parameter: Smoking disturbed
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)	mCC (N=32)	SA (N=9)
		Value	Value	Value
Baseline	n	46	30	8
	Missing, n(%)	1 (2.1)	2 (6.3)	1 (11.1)
	Mean (SD)	2.74 (1.182)	3.00 (1.204)	3.00 (1.070)
	95% CI of Mean	2.38, 3.10	2.55, 3.45	2.10, 3.90
	Median	3.00	3.00	3.00
	Q25, Q75	2.00, 3.00	2.00, 3.00	2.00, 3.50
	Min, Max	1.0, 5.0	1.0, 5.0	2.0, 5.0
Day 90	n	44	22	
	Missing, n(%)	3 (6.4)	10 (31.3)	
	Mean (SD)	2.73 (1.020)	2.59 (1.260)	
	95% CI of Mean	2.41, 3.04	2.03, 3.15	
	Median	3.00	2.00	
	Q25, Q75	2.00, 3.00	2.00, 3.00	
	Min, Max	1.0, 5.0	1.0, 5.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.
Appendix 15.3.7.1

**Table 15.2.4.59.1 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - FAS****Parameter: Are you currently a smoker?**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	77	41	39
	n (%) Yes, I currently smoke	77 (100)	41 (100)	39 (100)
	n (%) No, I quit within the last 6 months	0	0	0
	n (%) No, I quit more than 6 months ago	0	0	0
	n (%) No, I have never smoked	0	0	0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.1 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - FAS****Parameter: Are you currently a smoker?**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	73	35	32
	n (%) Yes, I currently smoke	73 (100)	35 (100)	20 (62.5)
	n (%) No, I quit within the last 6 months	0	0	11 (34.4)
	n (%) No, I quit more than 6 months ago	0	0	0
	n (%) No, I have never smoked	0	0	1 (3.1)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.1 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - FAS****Parameter: Are you currently a smoker?**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	72	36	30
	n (%) Yes, I currently smoke	72 (100)	36 (100)	20 (66.7)
	n (%) No, I quit within the last 6 months	0	0	10 (33.3)
	n (%) No, I quit more than 6 months ago	0	0	0
	n (%) No, I have never smoked	0	0	0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.1 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - FAS****Parameter: Are you currently a smoker?**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	67	29	29
	n (%) Yes, I currently smoke	67 (100)	29 (100)	23 (79.3)
	n (%) No, I quit within the last 6 months	0	0	6 (20.7)
	n (%) No, I quit more than 6 months ago	0	0	0
	n (%) No, I have never smoked	0	0	0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.1 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - FAS****Parameter: How many times did you quit smoking?**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	77	41	39
	n (%) 0 times	62 (80.5)	34 (82.9)	26 (66.7)
	n (%) 1 time	6 (7.8)	3 (7.3)	6 (15.4)
	n (%) 2 times	4 (5.2)	2 (4.9)	3 (7.7)
	n (%) 3 times	3 (3.9)	2 (4.9)	3 (7.7)
	n (%) 4 times	1 (1.3)	0	0
	n (%) 10 times	1 (1.3)	0	1 (2.6)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.1 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - FAS****Parameter: How many times did you quit smoking?**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	67	33	31
	n (%) 0 times	59 (88.1)	27 (81.8)	7 (22.6)
	n (%) 1 time	4 (6.0)	4 (12.1)	10 (32.3)
	n (%) 2 times	1 (1.5)	0	4 (12.9)
	n (%) 3 times	3 (4.5)	2 (6.1)	2 (6.5)
	n (%) 4 times	0	0	2 (6.5)
	n (%) 5 times	0	0	1 (3.2)
	n (%) 6 times	0	0	1 (3.2)
	n (%) 9 times	0	0	1 (3.2)
	n (%) 10 times	0	0	1 (3.2)
	n (%) 13 times	0	0	1 (3.2)
	n (%) 100 times	0	0	1 (3.2)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.1 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - FAS****Parameter: How many times did you quit smoking?**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	63	33	25
	n (%) 0 times	51 (81.0)	30 (90.9)	5 (20.0)
	n (%) 1 time	4 (6.3)	2 (6.1)	5 (20.0)
	n (%) 2 times	5 (7.9)	0	5 (20.0)
	n (%) 3 times	2 (3.2)	1 (3.0)	3 (12.0)
	n (%) 4 times	0	0	1 (4.0)
	n (%) 5 times	0	0	1 (4.0)
	n (%) 8 times	0	0	2 (8.0)
	n (%) 10 times	1 (1.6)	0	2 (8.0)
	n (%) 15 times	0	0	1 (4.0)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.1 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - FAS****Parameter: How many times did you quit smoking?**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	66	27	25
	n (%) 0 times	59 (89.4)	23 (85.2)	5 (20.0)
	n (%) 1 time	4 (6.1)	3 (11.1)	5 (20.0)
	n (%) 2 times	1 (1.5)	0	0
	n (%) 3 times	1 (1.5)	1 (3.7)	3 (12.0)
	n (%) 4 times	0	0	3 (12.0)
	n (%) 5 times	0	0	1 (4.0)
	n (%) 9 times	0	0	1 (4.0)
	n (%) 10 times	1 (1.5)	0	1 (4.0)
	n (%) 15 times	0	0	1 (4.0)
	n (%) 20 times	0	0	2 (8.0)
	n (%) 25 times	0	0	1 (4.0)
	n (%) 40 times	0	0	1 (4.0)
	n (%) 50 times	0	0	1 (4.0)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.1 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - FAS****Parameter: Seriously thinking of quitting smoking?**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Baseline	n	77	41	39
	n (%) Yes, within the next 30 days	0	1 (2.4)	0
	n (%) Yes, within the next 6 months	0	0	0
	n (%) No, not thinking of quitting	77 (100)	40 (97.6)	39 (100)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.1 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - FAS****Parameter: Seriously thinking of quitting smoking?**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 30	n	73	35	31
	n (%) Yes, within the next 30 days	0	0	6 (19.4)
	n (%) Yes, within the next 6 months	3 (4.1)	1 (2.9)	3 (9.7)
	n (%) No, not thinking of quitting	70 (95.9)	34 (97.1)	22 (71.0)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.1 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - FAS****Parameter: Seriously thinking of quitting smoking?**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 60	n	72	36	28
	n (%) Yes, within the next 30 days	2 (2.8)	0	3 (10.7)
	n (%) Yes, within the next 6 months	7 (9.7)	1 (2.8)	2 (7.1)
	n (%) No, not thinking of quitting	63 (87.5)	35 (97.2)	23 (82.1)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.1 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - FAS****Parameter: Seriously thinking of quitting smoking?**

Timepoint	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)
		Value	Value	Value
Day 90	n	67	29	25
	n (%) Yes, within the next 30 days	7 (10.4)	4 (13.8)	7 (28.0)
	n (%) Yes, within the next 6 months	8 (11.9)	1 (3.4)	2 (8.0)
	n (%) No, not thinking of quitting	52 (77.6)	24 (82.8)	16 (64.0)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population****Parameter: Are you currently a smoker?****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	73	35	24
	n (%) Yes, I currently smoke	73 (100)	35 (100)	24 (100)
	n (%) No, I quit within the last 6 months	0	0	0
	n (%) No, I quit more than 6 months ago	0	0	0
	n (%) No, I have never smoked	0	0	0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population****Parameter: Are you currently a smoker?****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=32)	mCC (N=34)	SA (N=8)
		Value	Value	Value
Baseline	n	31	34	8
	n (%) Yes, I currently smoke	31 (100)	34 (100)	8 (100)
	n (%) No, I quit within the last 6 months	0	0	0
	n (%) No, I quit more than 6 months ago	0	0	0
	n (%) No, I have never smoked	0	0	0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population****Parameter: Are you currently a smoker?****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=32)	mCC (N=34)	SA (N=8)
		Value	Value	Value
Day 30	n	30	29	8
	n (%) Yes, I currently smoke	30 (100)	29 (100)	3 (37.5)
	n (%) No, I quit within the last 6 months	0	0	5 (62.5)
	n (%) No, I quit more than 6 months ago	0	0	0
	n (%) No, I have never smoked	0	0	0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population****Parameter: Are you currently a smoker?****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=36)	mCC (N=34)	SA (N=7)
		Value	Value	Value
Baseline	n	34	34	7
	n (%) Yes, I currently smoke	34 (100)	34 (100)	7 (100)
	n (%) No, I quit within the last 6 months	0	0	0
	n (%) No, I quit more than 6 months ago	0	0	0
	n (%) No, I have never smoked	0	0	0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population****Parameter: Are you currently a smoker?****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=36)	mCC (N=34)	SA (N=7)
		Value	Value	Value
Day 60	n	36	31	6
	n (%) Yes, I currently smoke	36 (100)	31 (100)	2 (33.3)
	n (%) No, I quit within the last 6 months	0	0	4 (66.7)
	n (%) No, I quit more than 6 months ago	0	0	0
	n (%) No, I have never smoked	0	0	0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population****Parameter: Are you currently a smoker?****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=41)	mCC (N=31)	SA (N=7)
		Value	Value	Value
Baseline	n	39	31	7
	n (%) Yes, I currently smoke	39 (100)	31 (100)	7 (100)
	n (%) No, I quit within the last 6 months	0	0	0
	n (%) No, I quit more than 6 months ago	0	0	0
	n (%) No, I have never smoked	0	0	0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population****Parameter: Are you currently a smoker?****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=41)	mCC (N=31)	SA (N=7)
		Value	Value	Value
Day 90	n	39	25	6
	n (%) Yes, I currently smoke	39 (100)	25 (100)	3 (50.0)
	n (%) No, I quit within the last 6 months	0	0	3 (50.0)
	n (%) No, I quit more than 6 months ago	0	0	0
	n (%) No, I have never smoked	0	0	0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population****Parameter: How many times did you quit smoking?****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	73	35	24
	n (%) 0 times	59 (80.8)	30 (85.7)	16 (66.7)
	n (%) 1 time	6 (8.2)	1 (2.9)	3 (12.5)
	n (%) 2 times	4 (5.5)	2 (5.7)	3 (12.5)
	n (%) 3 times	2 (2.7)	2 (5.7)	1 (4.2)
	n (%) 4 times	1 (1.4)	0	0
	n (%) 10 times	1 (1.4)	0	1 (4.2)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population**

Parameter: How many times did you quit smoking?
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=32)	mCC (N=34)	SA (N=8)
		Value	Value	Value
Baseline	n	31	34	8
	n (%) 0 times	27 (87.1)	29 (85.3)	6 (75.0)
	n (%) 1 time	0	1 (2.9)	1 (12.5)
	n (%) 2 times	2 (6.5)	2 (5.9)	0
	n (%) 3 times	1 (3.2)	2 (5.9)	1 (12.5)
	n (%) 10 times	1 (3.2)	0	0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population**

Parameter: How many times did you quit smoking?
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=32)	mCC (N=34)	SA (N=8)
		Value	Value	Value
Day 30	n	28	28	6
	n (%) 0 times	26 (92.9)	23 (82.1)	2 (33.3)
	n (%) 1 time	1 (3.6)	3 (10.7)	2 (33.3)
	n (%) 3 times	1 (3.6)	2 (7.1)	2 (33.3)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population**

Parameter: How many times did you quit smoking?
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=36)	mCC (N=34)	SA (N=7)
		Value	Value	Value
Baseline	n	34	34	7
	n (%) 0 times	31 (91.2)	29 (85.3)	4 (57.1)
	n (%) 1 time	1 (2.9)	1 (2.9)	2 (28.6)
	n (%) 2 times	1 (2.9)	2 (5.9)	0
	n (%) 3 times	1 (2.9)	2 (5.9)	1 (14.3)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population****Parameter: How many times did you quit smoking?****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=36)	mCC (N=34)	SA (N=7)
		Value	Value	Value
Day 60	n	32	29	4
	n (%) 0 times	25 (78.1)	27 (93.1)	0
	n (%) 1 time	2 (6.3)	1 (3.4)	3 (75.0)
	n (%) 2 times	3 (9.4)	0	1 (25.0)
	n (%) 3 times	1 (3.1)	1 (3.4)	0
	n (%) 10 times	1 (3.1)	0	0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population**

Parameter: How many times did you quit smoking?
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=41)	mCC (N=31)	SA (N=7)
		Value	Value	Value
Baseline	n	39	31	7
	n (%) 0 times	35 (89.7)	26 (83.9)	4 (57.1)
	n (%) 1 time	1 (2.6)	1 (3.2)	2 (28.6)
	n (%) 2 times	2 (5.1)	2 (6.5)	0
	n (%) 3 times	1 (2.6)	2 (6.5)	1 (14.3)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population**

Parameter: How many times did you quit smoking?
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=41)	mCC (N=31)	SA (N=7)
		Value	Value	Value
Day 90	n	39	23	5
	n (%) 0 times	34 (87.2)	20 (87.0)	2 (40.0)
	n (%) 1 time	3 (7.7)	2 (8.7)	2 (40.0)
	n (%) 2 times	1 (2.6)	0	0
	n (%) 3 times	0	1 (4.3)	1 (20.0)
	n (%) 10 times	1 (2.6)	0	0

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population**

Parameter: Seriously thinking of quitting smoking?
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)	mCC (N=35)	SA (N=24)
		Value	Value	Value
Baseline	n	73	35	24
	n (%) Yes, within the next 30 days	0	0	0
	n (%) Yes, within the next 6 months	0	0	0
	n (%) No, not thinking of quitting	73 (100)	35 (100)	24 (100)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population**

Parameter: Seriously thinking of quitting smoking?
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=32)	mCC (N=34)	SA (N=8)
		Value	Value	Value
Baseline	n	31	34	8
	n (%) Yes, within the next 30 days	0	0	0
	n (%) Yes, within the next 6 months	0	0	0
	n (%) No, not thinking of quitting	31 (100)	34 (100)	8 (100)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population**

Parameter: Seriously thinking of quitting smoking?
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=32)	mCC (N=34)	SA (N=8)
		Value	Value	Value
Day 30	n	30	29	6
	n (%) Yes, within the next 30 days	0	0	1 (16.7)
	n (%) Yes, within the next 6 months	1 (3.3)	1 (3.4)	1 (16.7)
	n (%) No, not thinking of quitting	29 (96.7)	28 (96.6)	4 (66.7)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population**

Parameter: Seriously thinking of quitting smoking?
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=36)	mCC (N=34)	SA (N=7)
		Value	Value	Value
Baseline	n	34	34	7
	n (%) Yes, within the next 30 days	0	0	0
	n (%) Yes, within the next 6 months	0	0	0
	n (%) No, not thinking of quitting	34 (100)	34 (100)	7 (100)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population**

Parameter: Seriously thinking of quitting smoking?
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=36)	mCC (N=34)	SA (N=7)
		Value	Value	Value
Day 60	n	36	31	4
	n (%) Yes, within the next 30 days	1 (2.8)	0	0
	n (%) Yes, within the next 6 months	5 (13.9)	1 (3.2)	1 (25.0)
	n (%) No, not thinking of quitting	30 (83.3)	30 (96.8)	3 (75.0)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population**

Parameter: Seriously thinking of quitting smoking?
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=41)	mCC (N=31)	SA (N=7)
		Value	Value	Value
Baseline	n	39	31	7
	n (%) Yes, within the next 30 days	0	0	0
	n (%) Yes, within the next 6 months	0	0	0
	n (%) No, not thinking of quitting	39 (100)	31 (100)	7 (100)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.59.2 Descriptive Statistics of Prochaska 'Stage of Change' Questionnaire Results - Compliant Population**

Parameter: Seriously thinking of quitting smoking?
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=41)	mCC (N=31)	SA (N=7)
		Value	Value	Value
Day 90	n	39	25	4
	n (%) Yes, within the next 30 days	6 (15.4)	2 (8.0)	1 (25.0)
	n (%) Yes, within the next 6 months	5 (12.8)	1 (4.0)	1 (25.0)
	n (%) No, not thinking of quitting	28 (71.8)	22 (88.0)	2 (50.0)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	13.32 (3.555)		13.68 (4.221)		13.94 (3.132)	
	95% CI of Mean	12.35, 14.28		11.89, 15.47		12.33, 15.56	
	Median	12.79		12.16		14.00	
	Q25, Q75	10.80, 15.00		10.27, 15.21		12.75, 15.00	
	Min, Max	5.8, 22.1		8.6, 24.8		8.0, 20.4	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	14.64 (3.818)	15.10 (29.272)	13.87 (3.636)	-0.11 (11.268)		
	95% CI of Mean	13.60, 15.68	6.50, 23.70	12.33, 15.41	-4.98, 4.77		
	Median	14.20	13.56	13.08	2.41		
	Q25, Q75	12.20, 16.11	-3.76, 32.44	11.61, 16.05	-7.31, 6.06		
	Min, Max	8.0, 27.6	-48.8, 82.1	8.5, 20.1	-21.9, 24.0		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	15.10 (3.291)	17.94 (29.521)	13.36 (3.633)	-1.42 (16.885)		
	95% CI of Mean	14.22, 15.98	9.16, 26.71	11.86, 14.87	-9.11, 6.27		
	Median	14.65	10.83	13.00	-2.22		
	Q25, Q75	13.11, 16.33	-3.23, 33.06	11.00, 15.50	-10.00, 5.08		
	Min, Max	10.2, 26.1	-32.7, 103.5	7.1, 20.9	-30.3, 38.1		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	13.48 (3.555)		13.60 (4.281)		13.54 (2.671)	
	95% CI of Mean	12.13, 14.84		11.78, 15.41		11.63, 15.46	
	Median	13.56		12.16		13.92	
	Q25, Q75	10.80, 15.00		10.23, 15.21		12.75, 14.57	
	Min, Max	6.5, 22.1		8.6, 24.8		8.0, 17.7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	15.74 (4.723)	20.61 (38.599)	13.13 (4.601)	-0.10 (21.848)		
	95% CI of Mean	14.01, 17.48	4.67, 36.54	11.18, 15.07	-11.34, 11.14		
	Median	15.00	26.34	13.50	-3.99		
	Q25, Q75	13.50, 17.00	-10.88, 44.62	9.75, 15.17	-13.00, 3.70		
	Min, Max	9.5, 32.3	-36.7, 127.3	3.0, 27.0	-26.7, 53.3		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	13.54 (4.037)		13.52 (4.206)		14.61 (2.127)	
	95% CI of Mean	11.97, 15.11		11.78, 15.27		12.97, 16.25	
	Median	13.36		12.13		14.57	
	Q25, Q75	9.89, 16.80		10.25, 15.00		13.56, 16.20	
	Min, Max	6.5, 22.1		8.6, 24.8		10.9, 17.7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	15.77 (4.833)	19.86 (31.471)	14.21 (4.112)	-2.99 (15.380)		
	95% CI of Mean	13.72, 17.81	5.13, 34.60	12.09, 16.33	-12.76, 6.79		
	Median	15.00	11.82	14.33	-0.88		
	Q25, Q75	14.00, 16.50	0.56, 50.27	11.50, 17.00	-15.47, 5.26		
	Min, Max	7.8, 34.5	-31.6, 75.8	6.5, 23.0	-25.5, 23.6		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	13.51 (3.789)		13.53 (4.376)		13.82 (1.877)	
	95% CI of Mean	12.18, 14.83		11.64, 15.43		11.85, 15.80	
	Median	13.36		12.10		14.06	
	Q25, Q75	10.33, 16.60		10.20, 15.43		12.75, 15.00	
	Min, Max	6.5, 22.1		8.6, 24.8		10.9, 16.2	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total number of puffs (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	15.55 (4.914)	22.17 (43.546)	12.78 (5.359)	-8.25 (18.945)		
	95% CI of Mean	13.91, 17.20	4.57, 39.76	10.11, 15.45	-19.70, 3.21		
	Median	15.50	11.06	12.00	-12.79		
	Q25, Q75	13.33, 17.67	0.64, 55.70	7.50, 14.00	-21.25, 0.00		
	Min, Max	5.0, 28.5	-61.1, 130.9	7.0, 24.5	-32.6, 28.2		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	644.71 (286.874)		689.64 (368.383)		691.03 (308.154)	
	95% CI of Mean	567.15, 722.27		534.08, 845.20		532.59, 849.47	
	Median	595.49		605.00		682.69	
	Q25, Q75	473.80, 688.11		465.05, 747.48		510.56, 776.37	
	Min, Max	308.7, 1914.9		349.4, 2051.6		349.1, 1714.1	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	790.71 (310.635)	37.18 (66.300)	668.14 (325.122)	-0.88 (14.848)		
	95% CI of Mean	706.73, 874.70	17.71, 56.65	530.85, 805.43	-7.31, 5.54		
	Median	756.37	22.11	589.46	-2.26		
	Q25, Q75	568.20, 982.58	-8.94, 72.29	441.49, 789.94	-10.97, 10.46		
	Min, Max	253.5, 1611.8	-78.2, 212.6	336.0, 1690.8	-34.2, 25.3		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set**

Parameter: Total puff volume (mL) (average over visit)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	882.74 (307.439)	49.03 (71.137)	668.83 (333.091)	2.97 (22.874)		
	95% CI of Mean	801.16, 964.32	27.90, 70.16	531.33, 806.33	-7.45, 13.39		
	Median	854.26	34.97	574.87	0.81		
	Q25, Q75	678.09, 1076.17	-5.23, 83.89	443.59, 766.37	-12.12, 16.83		
	Min, Max	378.2, 2050.3	-64.1, 267.5	320.5, 1798.3	-34.3, 44.8		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	641.52 (276.517)		694.28 (365.026)		631.99 (181.573)	
	95% CI of Mean	536.33, 746.70		540.13, 848.42		502.10, 761.89	
	Median	600.01		605.00		655.39	
	Q25, Q75	458.75, 688.11		490.47, 747.48		453.19, 776.37	
	Min, Max	337.0, 1400.5		349.4, 2051.6		374.8, 899.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	790.73 (274.918)	38.92 (56.763)	699.15 (326.148)	1.99 (32.889)		
	95% CI of Mean	689.89, 891.58	15.49, 62.36	561.43, 836.88	-14.93, 18.90		
	Median	826.04	36.15	616.90	-9.85		
	Q25, Q75	617.32, 966.90	8.91, 91.00	518.03, 776.24	-20.29, 13.66		
	Min, Max	219.1, 1357.9	-74.6, 117.8	235.2, 1605.1	-33.2, 95.0		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	628.31 (243.281)		681.77 (362.768)		602.73 (154.672)	
	95% CI of Mean	533.97, 722.65		532.02, 831.52		483.83, 721.63	
	Median	593.54		600.27		572.97	
	Q25, Q75	470.40, 672.28		488.07, 735.63		501.20, 759.64	
	Min, Max	337.0, 1400.5		349.4, 2051.6		374.8, 793.1	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	851.99 (344.711)	55.59 (78.376)	688.09 (265.165)	-4.21 (27.333)		
	95% CI of Mean	706.42, 997.55	18.90, 92.27	551.75, 824.43	-21.58, 13.16		
	Median	860.05	39.44	656.59	-1.49		
	Q25, Q75	575.57, 997.21	-2.95, 90.66	543.56, 802.77	-16.47, 8.01		
	Min, Max	306.7, 1708.8	-32.7, 272.5	290.1, 1438.1	-63.1, 38.3		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff volume (mL) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	617.93 (228.727)		681.53 (378.226)		606.07 (168.740)	
	95% CI of Mean	538.12, 697.75		517.97, 845.10		428.99, 783.16	
	Median	596.77		591.86		627.83	
	Q25, Q75	467.00, 677.66		442.02, 735.63		453.19, 759.64	
	Min, Max	337.0, 1400.5		349.4, 2051.6		374.8, 793.1	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set**

Parameter: Total puff volume (mL) (average over visit)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	766.93 (305.360)	39.28 (67.821)	610.71 (374.110)	-3.34 (28.798)		
	95% CI of Mean	665.12, 868.75	11.88, 66.67	424.67, 796.76	-20.75, 14.07		
	Median	764.81	41.84	512.15	-7.91		
	Q25, Q75	583.80, 927.62	5.03, 84.65	367.22, 814.99	-24.06, 8.81		
	Min, Max	154.0, 1433.3	-72.8, 204.5	164.6, 1448.4	-48.5, 52.5		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set**

Parameter: Average puff volume (mL) (average over visit)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	49.49 (17.360)		50.80 (18.191)		50.81 (20.201)	
	95% CI of Mean	44.79, 54.19		43.11, 58.48		40.42, 61.20	
	Median	47.17		49.95		45.91	
	Q25, Q75	36.30, 55.96		40.81, 59.56		36.41, 57.52	
	Min, Max	20.5, 110.8		19.7, 95.4		25.4, 110.4	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	56.41 (24.300)	16.96 (45.109)	48.45 (18.286)	-0.81 (9.859)		
	95% CI of Mean	49.83, 62.98	3.72, 30.21	40.73, 56.18	-5.08, 3.46		
	Median	53.38	12.15	46.87	-1.52		
	Q25, Q75	40.67, 68.32	-7.65, 38.08	36.68, 57.83	-5.22, 2.71		
	Min, Max	13.8, 164.3	-78.2, 159.3	22.7, 108.7	-28.8, 19.5		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	61.10 (26.919)	25.75 (50.931)	50.73 (19.797)	4.38 (15.162)		
	95% CI of Mean	53.95, 68.25	10.62, 40.88	42.56, 58.91	-2.53, 11.28		
	Median	60.28	12.65	51.55	1.67		
	Q25, Q75	43.42, 70.62	-5.01, 48.39	39.56, 59.26	-0.33, 9.74		
	Min, Max	15.8, 201.9	-55.3, 223.2	18.6, 116.0	-23.3, 50.7		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	48.08 (14.719)		51.47 (17.777)		48.71 (16.473)	
	95% CI of Mean	42.48, 53.68		43.96, 58.98		36.92, 60.50	
	Median	47.59		49.95		54.19	
	Q25, Q75	36.30, 55.96		41.95, 59.56		33.56, 62.27	
	Min, Max	25.6, 87.7		19.7, 95.4		25.4, 70.4	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	51.91 (18.814)	14.39 (38.480)	54.31 (17.350)	1.66 (21.505)		
	95% CI of Mean	45.00, 58.81	-1.50, 30.28	46.98, 61.64	-9.40, 12.73		
	Median	55.07	13.99	50.97	-2.90		
	Q25, Q75	39.23, 64.41	-8.66, 43.84	44.00, 58.99	-7.91, 6.14		
	Min, Max	19.0, 100.0	-61.9, 98.0	34.5, 113.8	-20.6, 74.9		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	47.95 (13.613)		50.71 (17.814)		43.03 (16.271)	
	95% CI of Mean	42.67, 53.24		43.35, 58.06		30.52, 55.55	
	Median	48.47		49.31		35.52	
	Q25, Q75	35.76, 56.63		41.63, 58.56		30.26, 55.58	
	Min, Max	26.8, 76.0		19.7, 95.4		25.4, 70.4	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	58.03 (28.725)	30.97 (54.470)	51.12 (19.730)	-1.81 (21.633)		
	95% CI of Mean	45.90, 70.17	5.47, 56.47	40.97, 61.27	-15.56, 11.94		
	Median	53.51	19.61	49.69	-0.50		
	Q25, Q75	46.94, 64.52	-5.47, 64.29	38.46, 57.82	-11.15, 8.46		
	Min, Max	12.6, 153.3	-56.4, 161.2	17.3, 102.7	-53.1, 36.2		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	47.07 (13.048)		50.66 (18.604)		45.51 (17.583)	
	95% CI of Mean	42.51, 51.62		42.61, 58.71		27.06, 63.97	
	Median	45.72		48.98		40.72	
	Q25, Q75	36.30, 54.58		39.99, 60.57		33.56, 62.27	
	Min, Max	25.6, 76.0		19.7, 95.4		25.4, 70.4	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff volume (mL) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	50.39 (17.049)	13.16 (40.283)	49.51 (24.963)	5.37 (20.632)		
	95% CI of Mean	44.70, 56.08	-3.12, 29.43	37.09, 61.93	-7.10, 17.84		
	Median	48.61	2.78	42.75	5.98		
	Q25, Q75	40.42, 60.39	-14.86, 48.42	34.14, 63.79	-6.64, 15.08		
	Min, Max	7.7, 88.5	-73.2, 88.0	11.8, 101.2	-32.4, 39.8		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	1.63 (0.511)		1.81 (0.735)		1.68 (0.453)	
	95% CI of Mean	1.49, 1.77		1.49, 2.12		1.44, 1.91	
	Median	1.66		1.75		1.64	
	Q25, Q75	1.16, 1.97		1.26, 2.26		1.54, 1.80	
	Min, Max	0.7, 3.5		0.5, 3.3		1.0, 2.6	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	2.06 (0.800)	25.79 (37.459)	1.82 (0.752)	4.05 (9.262)		
	95% CI of Mean	1.83, 2.28	14.79, 36.80	1.49, 2.14	0.04, 8.06		
	Median	1.92	16.55	1.70	3.00		
	Q25, Q75	1.39, 2.67	0.39, 50.80	1.16, 2.46	-4.10, 13.72		
	Min, Max	0.7, 3.8	-36.3, 163.6	0.4, 3.2	-13.3, 18.8		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	2.31 (1.025)	33.70 (38.830)	1.70 (0.692)	4.41 (17.494)		
	95% CI of Mean	2.04, 2.59	22.16, 45.24	1.41, 1.99	-3.56, 12.37		
	Median	2.27	34.08	1.51	1.63		
	Q25, Q75	1.70, 2.79	5.35, 50.85	1.23, 2.24	-4.66, 9.84		
	Min, Max	0.8, 5.7	-29.0, 182.5	0.4, 3.3	-22.3, 58.0		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set**

Parameter: Average puff duration (s) (average over visit)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	1.61 (0.400)		1.85 (0.710)		1.69 (0.388)	
	95% CI of Mean	1.45, 1.76		1.54, 2.15		1.41, 1.97	
	Median	1.59		1.86		1.62	
	Q25, Q75	1.23, 1.93		1.36, 2.26		1.54, 1.73	
	Min, Max	0.9, 2.3		0.5, 3.3		1.2, 2.6	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	1.94 (0.757)	21.67 (34.816)	1.88 (0.610)	-3.90 (11.521)		
	95% CI of Mean	1.65, 2.22	7.30, 36.05	1.62, 2.14	-9.83, 2.02		
	Median	1.89	25.02	1.92	-0.74		
	Q25, Q75	1.45, 2.45	-5.45, 44.25	1.42, 2.31	-6.05, 3.36		
	Min, Max	0.7, 3.8	-38.4, 109.1	0.7, 3.0	-29.8, 10.1		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	1.61 (0.426)		1.81 (0.719)		1.42 (0.275)	
	95% CI of Mean	1.44, 1.78		1.51, 2.11		1.21, 1.64	
	Median	1.64		1.84		1.54	
	Q25, Q75	1.27, 1.93		1.35, 2.22		1.16, 1.62	
	Min, Max	0.7, 2.3		0.5, 3.3		1.0, 1.7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	2.10 (0.897)	30.84 (36.822)	1.81 (0.802)	1.15 (12.161)		
	95% CI of Mean	1.72, 2.48	13.60, 48.08	1.39, 2.23	-6.58, 8.88		
	Median	2.02	21.64	1.72	2.49		
	Q25, Q75	1.49, 2.58	8.36, 52.78	1.35, 2.44	-8.82, 5.75		
	Min, Max	0.8, 4.0	-25.1, 112.9	0.4, 3.2	-14.7, 27.1		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	1.59 (0.428)		1.76 (0.725)		1.47 (0.256)	
	95% CI of Mean	1.44, 1.74		1.44, 2.08		1.20, 1.74	
	Median	1.64		1.65		1.54	
	Q25, Q75	1.22, 1.93		1.17, 2.10		1.39, 1.62	
	Min, Max	0.7, 2.3		0.5, 3.3		1.0, 1.7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average puff duration (s) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	2.10 (0.846)	24.70 (35.519)	1.56 (0.742)	0.46 (15.700)		
	95% CI of Mean	1.81, 2.38	10.35, 39.05	1.19, 1.94	-9.03, 9.96		
	Median	1.98	19.68	1.58	1.06		
	Q25, Q75	1.39, 2.68	-4.60, 54.78	1.21, 2.04	-14.04, 14.77		
	Min, Max	0.9, 4.8	-28.6, 96.7	0.3, 3.1	-26.5, 21.3		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	20.74 (5.594)		23.53 (9.613)		23.14 (7.917)	
	95% CI of Mean	19.23, 22.26		19.46, 27.59		19.06, 27.21	
	Median	19.94		20.63		21.03	
	Q25, Q75	17.21, 23.23		16.07, 32.40		18.57, 24.42	
	Min, Max	12.8, 42.6		10.1, 42.8		12.6, 39.6	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	29.49 (11.739)	46.41 (60.495)	24.27 (10.513)	3.94 (15.009)		
	95% CI of Mean	26.31, 32.66	28.65, 64.18	19.83, 28.71	-2.55, 10.44		
	Median	29.69	41.42	22.52	4.60		
	Q25, Q75	20.80, 38.94	1.34, 73.89	16.69, 29.73	-6.13, 18.40		
	Min, Max	7.5, 54.1	-59.6, 219.6	8.8, 45.4	-18.5, 28.6		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	33.96 (14.631)	56.57 (61.430)	21.88 (9.554)	3.02 (25.820)		
	95% CI of Mean	30.07, 37.85	38.33, 74.82	17.93, 25.83	-8.74, 14.78		
	Median	31.35	43.20	19.06	-0.44		
	Q25, Q75	21.63, 43.00	12.87, 88.56	15.18, 29.44	-14.16, 18.06		
	Min, Max	12.4, 80.1	-33.8, 249.9	8.7, 45.4	-30.5, 71.9		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	20.97 (5.962)		23.85 (9.302)		22.44 (5.383)	
	95% CI of Mean	18.69, 23.24		19.92, 27.78		18.59, 26.30	
	Median	19.11		20.63		21.55	
	Q25, Q75	17.93, 22.62		17.10, 32.40		18.79, 24.42	
	Min, Max	12.8, 42.6		10.1, 42.8		15.8, 35.5	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	29.87 (12.027)	46.95 (55.526)	23.52 (8.562)	-4.31 (22.791)		
	95% CI of Mean	25.45, 34.28	24.02, 69.87	19.90, 27.14	-16.03, 7.42		
	Median	32.75	50.55	21.81	-3.93		
	Q25, Q75	21.40, 36.36	25.71, 76.26	17.73, 29.53	-19.11, 6.74		
	Min, Max	8.1, 60.2	-56.5, 162.9	6.7, 40.1	-36.5, 57.2		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	20.84 (6.079)		23.34 (9.457)		20.46 (3.195)	
	95% CI of Mean	18.48, 23.20		19.43, 27.25		18.00, 22.92	
	Median	19.21		20.62		20.48	
	Q25, Q75	17.57, 22.76		16.34, 32.30		18.59, 22.77	
	Min, Max	12.8, 42.6		10.1, 42.8		14.9, 24.9	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	32.04 (14.414)	56.83 (62.882)	23.84 (9.728)	-1.26 (24.692)		
	95% CI of Mean	25.95, 38.13	27.40, 86.27	18.83, 28.84	-16.96, 14.43		
	Median	29.83	46.32	22.92	-0.01		
	Q25, Q75	22.97, 37.44	28.04, 74.45	16.62, 30.77	-26.40, 13.16		
	Min, Max	11.8, 71.5	-37.0, 212.2	8.6, 42.4	-30.4, 50.4		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total puff duration (s) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	20.62 (5.763)		22.60 (9.508)		20.11 (3.513)	
	95% CI of Mean	18.61, 22.64		18.48, 26.72		16.42, 23.80	
	Median	19.21		20.53		19.73	
	Q25, Q75	17.21, 22.64		15.81, 32.30		18.59, 22.77	
	Min, Max	12.8, 42.6		10.1, 42.8		14.9, 24.9	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set**

Parameter: Total puff duration (s) (average over visit)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	32.40 (15.217)	55.69 (71.870)	18.45 (9.916)	-7.55 (26.206)		
	95% CI of Mean	27.32, 37.48	26.65, 84.72	13.52, 23.39	-23.39, 8.29		
	Median	32.31	55.35	16.44	-5.78		
	Q25, Q75	19.80, 41.91	18.95, 85.58	11.90, 19.92	-24.72, 10.29		
	Min, Max	6.3, 72.9	-72.1, 242.3	4.4, 43.9	-42.9, 47.7		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	33.11 (10.779)		31.53 (11.244)		32.11 (9.191)	
	95% CI of Mean	30.19, 36.03		26.78, 36.28		27.38, 36.84	
	Median	31.45		28.51		29.26	
	Q25, Q75	25.88, 38.62		24.44, 36.67		25.37, 39.22	
	Min, Max	17.3, 81.3		15.2, 63.1		17.7, 50.3	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	29.32 (8.658)	-7.32 (27.180)	30.15 (10.840)	-3.66 (7.816)		
	95% CI of Mean	26.97, 31.66	-15.30, 0.67	25.57, 34.74	-7.05, -0.28		
	Median	27.54	-6.00	26.90	-3.85		
	Q25, Q75	22.97, 34.96	-23.82, 6.25	21.52, 37.29	-11.20, 1.05		
	Min, Max	11.6, 51.6	-65.3, 77.0	15.2, 56.2	-15.3, 14.7		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	29.14 (8.528)	-5.82 (25.333)	32.91 (10.663)	1.65 (10.361)		
	95% CI of Mean	26.87, 31.40	-13.35, 1.71	28.50, 37.32	-3.07, 6.38		
	Median	29.52	-9.68	28.45	0.98		
	Q25, Q75	23.33, 34.02	-20.11, 12.54	26.03, 40.32	-4.25, 6.02		
	Min, Max	12.7, 51.6	-56.2, 64.1	20.2, 59.6	-18.6, 26.0		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	32.34 (9.622)		31.06 (11.276)		29.71 (7.968)	
	95% CI of Mean	28.68, 36.01		26.29, 35.82		24.01, 35.42	
	Median	31.03		27.92		27.38	
	Q25, Q75	24.40, 38.53		24.44, 35.45		24.83, 35.01	
	Min, Max	17.3, 54.4		15.2, 63.1		17.7, 43.7	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	29.22 (8.810)	-4.88 (30.389)	31.59 (9.968)	6.51 (21.360)		
	95% CI of Mean	25.99, 32.46	-17.43, 7.67	27.37, 35.80	-4.48, 17.50		
	Median	28.14	-6.20	27.44	-0.54		
	Q25, Q75	21.85, 35.67	-23.73, 13.89	24.78, 38.80	-5.92, 15.38		
	Min, Max	16.6, 45.5	-55.4, 71.3	17.5, 53.9	-14.6, 74.2		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	32.72 (7.149)		31.26 (11.087)		31.84 (10.662)	
	95% CI of Mean	29.95, 35.50		26.68, 35.84		23.64, 40.04	
	Median	32.26		28.47		28.75	
	Q25, Q75	27.56, 38.57		24.74, 36.22		24.83, 39.22	
	Min, Max	17.3, 46.6		15.2, 63.1		17.7, 50.3	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	30.26 (11.623)	2.15 (45.773)	31.61 (7.385)	-1.61 (21.383)		
	95% CI of Mean	25.34, 35.17	-19.27, 23.58	27.81, 35.42	-15.20, 11.98		
	Median	27.12	-4.99	30.09	-0.45		
	Q25, Q75	22.50, 37.68	-22.80, 14.92	27.33, 35.73	-9.28, 6.64		
	Min, Max	12.5, 59.5	-55.1, 108.2	18.3, 46.7	-45.9, 47.4		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	32.62 (8.404)		32.04 (11.212)		33.29 (12.930)	
	95% CI of Mean	29.69, 35.56		27.19, 36.89		19.72, 46.86	
	Median	31.64		28.56		32.36	
	Q25, Q75	26.24, 38.62		24.91, 37.13		23.36, 43.65	
	Min, Max	17.3, 54.1		15.2, 63.1		17.7, 50.3	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average flow (mL/s) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	27.24 (9.857)	-9.30 (25.577)	35.12 (16.069)	6.28 (14.574)		
	95% CI of Mean	23.95, 30.53	-19.64, 1.03	27.12, 43.12	-2.53, 15.09		
	Median	25.76	-2.11	29.82	3.84		
	Q25, Q75	21.62, 31.20	-29.11, 8.71	26.06, 37.23	-0.68, 14.55		
	Min, Max	9.5, 50.2	-65.6, 33.3	19.4, 79.0	-22.1, 33.1		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	49.05 (15.805)		47.01 (17.037)		47.15 (13.797)	
	95% CI of Mean	44.77, 53.33		39.81, 54.21		40.05, 54.25	
	Median	48.13		41.81		41.85	
	Q25, Q75	37.59, 58.41		35.94, 56.08		37.30, 57.93	
	Min, Max	25.4, 120.6		21.8, 98.5		25.9, 76.9	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	44.24 (13.463)	-6.10 (28.134)	45.16 (16.538)	-2.70 (8.185)		
	95% CI of Mean	40.60, 47.89	-14.36, 2.17	38.17, 52.15	-6.24, 0.85		
	Median	43.52	-6.43	38.61	-5.04		
	Q25, Q75	33.58, 53.07	-23.98, 9.51	34.05, 55.47	-8.45, 1.49		
	Min, Max	15.7, 68.8	-68.0, 69.4	20.7, 85.0	-13.9, 18.2		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	43.82 (12.699)	-4.58 (26.911)	48.95 (15.367)	2.42 (10.225)		
	95% CI of Mean	40.44, 47.19	-12.58, 3.41	42.60, 55.30	-2.24, 7.08		
	Median	43.92	-8.55	44.11	1.25		
	Q25, Q75	33.57, 51.50	-22.40, 17.95	37.93, 57.61	-5.43, 5.96		
	Min, Max	21.3, 73.0	-51.0, 59.1	26.8, 88.8	-11.3, 26.5		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set**

Parameter: Average Peak flow (mL/s) (average over visit)
Product Use Time Period: Period 2

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	47.73 (13.730)		46.45 (17.109)		43.36 (12.975)	
	95% CI of Mean	42.50, 52.95		39.23, 53.68		34.07, 52.65	
	Median	48.44		41.13		40.45	
	Q25, Q75	36.71, 56.82		35.94, 56.08		32.15, 56.34	
	Min, Max	25.4, 79.1		21.8, 98.5		25.9, 64.1	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	44.38 (14.602)	-3.51 (32.265)	47.04 (15.712)	5.21 (20.122)		
	95% CI of Mean	39.02, 49.74	-16.83, 9.81	40.40, 53.68	-5.14, 15.56		
	Median	44.89	-9.88	41.13	-0.46		
	Q25, Q75	32.24, 55.21	-30.47, 19.34	33.89, 60.26	-7.22, 10.78		
	Min, Max	23.2, 72.5	-54.6, 77.2	23.4, 80.5	-18.3, 67.9		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	49.06 (10.606)		46.65 (16.776)		45.90 (17.349)	
	95% CI of Mean	44.95, 53.18		39.72, 53.58		32.56, 59.24	
	Median	49.26		41.28		39.80	
	Q25, Q75	41.00, 57.69		35.99, 53.71		32.15, 57.93	
	Min, Max	26.0, 65.7		21.8, 98.5		25.9, 76.9	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	43.86 (15.946)	-3.55 (36.360)	47.21 (11.529)	-1.77 (20.956)		
	95% CI of Mean	37.13, 50.60	-20.57, 13.47	41.28, 53.15	-15.09, 11.54		
	Median	40.21	-6.68	50.50	-2.15		
	Q25, Q75	33.13, 58.46	-29.28, 16.74	40.18, 54.38	-10.54, 2.38		
	Min, Max	16.8, 72.5	-53.4, 66.0	24.5, 66.9	-44.8, 46.8		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	48.90 (12.068)		47.59 (17.190)		47.99 (21.100)	
	95% CI of Mean	44.69, 53.12		40.15, 55.02		25.84, 70.14	
	Median	49.26		42.33		45.04	
	Q25, Q75	38.56, 58.41		36.64, 58.46		30.90, 64.10	
	Min, Max	26.0, 79.1		21.8, 98.5		25.9, 76.9	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak flow (mL/s) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	41.75 (15.755)	-7.01 (28.546)	50.31 (21.038)	4.28 (12.153)		
	95% CI of Mean	36.49, 47.01	-18.54, 4.53	39.84, 60.78	-3.07, 11.63		
	Median	38.23	-6.36	42.81	3.09		
	Q25, Q75	33.67, 51.46	-25.92, 14.16	37.08, 55.37	1.61, 11.11		
	Min, Max	13.2, 79.9	-63.5, 39.1	29.5, 109.5	-22.4, 28.2		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	332.25 (85.340)		298.81 (62.633)		346.63 (81.003)	
	95% CI of Mean	309.17, 355.32		272.35, 325.26		304.97, 388.28	
	Median	351.25		285.84		341.57	
	Q25, Q75	260.24, 393.18		257.26, 344.65		300.60, 383.02	
	Min, Max	140.4, 554.0		195.3, 427.9		214.3, 533.5	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	243.21 (55.294)	-23.96 (32.253)	294.30 (72.873)	-2.85 (11.536)		
	95% CI of Mean	228.26, 258.16	-33.44, -14.49	263.53, 325.08	-7.84, 2.15		
	Median	241.91	-28.82	279.02	-1.10		
	Q25, Q75	203.45, 278.37	-41.96, -21.29	245.54, 341.97	-11.29, 5.61		
	Min, Max	94.7, 360.5	-66.6, 139.4	179.1, 451.9	-32.4, 17.7		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	230.05 (62.249)	-26.50 (37.704)	311.59 (86.989)	-2.12 (13.778)		
	95% CI of Mean	213.53, 246.57	-37.70, -15.29	275.68, 347.51	-8.40, 4.16		
	Median	239.25	-31.08	283.93	-0.06		
	Q25, Q75	194.99, 272.82	-45.05, -15.99	249.77, 367.17	-11.01, 4.94		
	Min, Max	92.4, 384.3	-69.4, 173.7	143.5, 510.9	-28.4, 21.7		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	336.56 (99.264)		299.20 (62.406)		365.66 (90.950)	
	95% CI of Mean	298.79, 374.32		272.85, 325.56		300.59, 430.73	
	Median	351.25		285.84		345.09	
	Q25, Q75	260.24, 397.33		259.14, 344.65		293.55, 434.42	
	Min, Max	140.4, 554.0		195.3, 427.9		242.2, 533.5	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	212.32 (72.970)	-34.32 (42.653)	316.68 (109.037)	2.85 (21.727)		
	95% CI of Mean	185.55, 239.09	-51.94, -16.71	270.63, 362.72	-8.33, 14.03		
	Median	222.18	-45.22	304.81	3.38		
	Q25, Q75	140.63, 269.61	-51.27, -28.30	249.82, 394.13	-6.68, 18.36		
	Min, Max	94.6, 352.8	-75.9, 151.3	33.8, 518.5	-41.5, 37.7		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	322.16 (101.289)		297.63 (61.594)		347.26 (104.581)	
	95% CI of Mean	282.88, 361.44		272.20, 323.06		266.87, 427.65	
	Median	296.14		285.31		340.65	
	Q25, Q75	245.55, 373.38		259.97, 340.57		272.01, 421.67	
	Min, Max	140.4, 554.0		195.3, 427.9		214.3, 533.5	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	223.98 (82.175)	-22.38 (48.116)	368.27 (125.606)	13.44 (27.979)		
	95% CI of Mean	189.28, 258.68	-44.91, 0.14	303.69, 432.86	-4.34, 31.23		
	Median	217.26	-24.87	304.15	8.25		
	Q25, Q75	153.38, 299.18	-52.19, -11.17	275.56, 474.22	1.07, 20.99		
	Min, Max	78.9, 348.3	-79.4, 146.1	235.2, 636.3	-23.9, 86.8		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total inter puff interval (s) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	331.65 (96.101)		294.08 (62.058)		322.85 (96.086)	
	95% CI of Mean	298.12, 365.19		267.24, 320.93		222.01, 423.69	
	Median	330.75		275.46		306.33	
	Q25, Q75	248.47, 397.33		254.55, 340.57		242.23, 421.67	
	Min, Max	140.4, 554.0		195.3, 427.9		214.3, 446.2	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set**

Parameter: Total inter puff interval (s) (average over visit)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	216.77 (71.807)	-27.07 (38.123)	323.43 (105.697)	6.92 (29.870)		
	95% CI of Mean	192.83, 240.72	-42.47, -11.66	270.86, 375.99	-11.13, 24.98		
	Median	200.93	-29.88	295.96	18.50		
	Q25, Q75	160.82, 262.54	-46.21, -13.86	271.24, 372.11	-15.77, 24.11		
	Min, Max	15.8, 332.2	-96.1, 120.7	163.7, 618.8	-40.4, 53.1		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	26.79 (8.585)		23.39 (6.140)		27.09 (10.074)	
	95% CI of Mean	24.47, 29.12		20.79, 25.98		21.91, 32.28	
	Median	26.04		22.90		23.75	
	Q25, Q75	20.72, 31.91		20.62, 25.94		20.97, 30.70	
	Min, Max	11.5, 49.9		13.4, 42.6		15.3, 56.5	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	18.05 (6.669)	-31.76 (27.876)	22.49 (5.976)	-1.43 (14.220)		
	95% CI of Mean	16.24, 19.85	-39.95, -23.57	19.96, 25.02	-7.58, 4.73		
	Median	16.66	-38.48	21.29	-5.06		
	Q25, Q75	12.96, 23.32	-50.08, -20.56	18.87, 26.17	-8.44, 7.68		
	Min, Max	7.3, 37.0	-67.5, 87.5	12.4, 43.0	-28.7, 40.5		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	16.35 (6.639)	-36.02 (33.350)	25.35 (9.929)	2.83 (23.889)		
	95% CI of Mean	14.58, 18.12	-45.93, -26.11	21.25, 29.45	-8.05, 13.71		
	Median	15.52	-44.71	23.32	5.71		
	Q25, Q75	11.45, 20.78	-53.79, -22.72	19.82, 28.63	-15.43, 14.16		
	Min, Max	5.9, 38.4	-73.9, 137.6	14.2, 52.2	-36.4, 48.3		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	26.67 (9.947)		23.55 (6.170)		28.87 (10.766)	
	95% CI of Mean	22.88, 30.45		20.94, 26.16		21.17, 36.58	
	Median	25.89		23.20		27.07	
	Q25, Q75	19.66, 29.30		20.62, 26.32		20.97, 31.19	
	Min, Max	11.5, 49.9		13.4, 42.6		19.1, 56.5	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	14.59 (7.304)	-42.86 (36.191)	25.46 (9.777)	5.99 (27.229)		
	95% CI of Mean	11.91, 17.28	-57.80, -27.92	21.33, 29.59	-8.01, 20.00		
	Median	11.69	-51.07	24.06	8.95		
	Q25, Q75	8.44, 18.42	-64.27, -32.30	19.28, 28.85	-18.13, 19.70		
	Min, Max	7.4, 32.3	-76.7, 99.9	11.3, 50.5	-44.0, 47.6		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	25.88 (10.456)		23.51 (6.044)		24.16 (6.050)	
	95% CI of Mean	21.82, 29.94		21.01, 26.01		19.51, 28.82	
	Median	24.22		23.03		21.47	
	Q25, Q75	18.38, 28.31		20.82, 26.14		20.39, 30.70	
	Min, Max	11.5, 49.9		13.4, 42.6		15.3, 32.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	15.64 (7.953)	-31.60 (40.374)	27.28 (8.314)	19.65 (43.344)		
	95% CI of Mean	12.28, 19.01	-50.50, -12.70	23.00, 31.56	-7.89, 47.20		
	Median	13.00	-43.97	27.56	9.30		
	Q25, Q75	9.76, 21.73	-56.69, -12.70	21.91, 29.99	-0.42, 24.32		
	Min, Max	5.7, 35.0	-86.4, 94.1	17.1, 46.2	-23.1, 145.4		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	26.54 (9.767)		23.32 (6.272)		24.05 (6.820)	
	95% CI of Mean	23.13, 29.96		20.60, 26.04		16.89, 31.21	
	Median	25.96		22.77		23.33	
	Q25, Q75	19.46, 33.39		20.42, 26.51		19.15, 31.19	
	Min, Max	11.5, 49.9		13.4, 42.6		15.3, 32.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average inter puff interval (s) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	15.57 (7.909)	-35.74 (36.586)	29.44 (14.523)	19.63 (36.493)		
	95% CI of Mean	12.92, 18.21	-50.52, -20.96	22.22, 36.67	-2.43, 41.69		
	Median	13.15	-39.75	25.28	12.43		
	Q25, Q75	9.58, 20.94	-60.48, -27.32	19.37, 39.15	-8.66, 53.37		
	Min, Max	3.2, 31.5	-90.7, 85.4	10.4, 69.0	-43.7, 67.7		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	352.99 (86.349)		322.33 (67.992)		369.76 (82.928)	
	95% CI of Mean	329.64, 376.34		293.62, 351.05		327.12, 412.40	
	Median	371.99		305.02		359.24	
	Q25, Q75	283.21, 412.35		273.92, 368.89		317.97, 419.35	
	Min, Max	153.1, 588.1		211.2, 465.2		229.2, 554.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	272.70 (53.293)	-19.96 (30.822)	318.57 (77.798)	-2.39 (11.052)		
	95% CI of Mean	258.29, 287.11	-29.02, -10.91	285.72, 351.43	-7.18, 2.39		
	Median	271.79	-25.66	307.00	-2.18		
	Q25, Q75	241.67, 303.18	-37.10, -9.09	259.16, 373.46	-10.89, 6.67		
	Min, Max	116.6, 384.6	-62.2, 132.1	193.9, 496.7	-30.5, 17.9		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	264.01 (62.370)	-21.64 (35.890)	333.47 (87.551)	-1.84 (12.939)		
	95% CI of Mean	247.46, 280.56	-32.31, -10.98	297.33, 369.62	-7.74, 4.05		
	Median	275.14	-24.95	313.72	0.84		
	Q25, Q75	221.89, 310.95	-43.50, -12.58	279.50, 385.44	-11.52, 4.83		
	Min, Max	119.9, 402.4	-63.0, 162.7	155.8, 523.3	-26.2, 23.2		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	357.52 (100.734)		323.05 (67.516)		388.10 (90.295)	
	95% CI of Mean	319.20, 395.84		294.54, 351.57		323.50, 452.70	
	Median	371.99		305.02		365.60	
	Q25, Q75	283.21, 415.24		279.99, 368.89		317.97, 450.24	
	Min, Max	153.1, 588.1		211.2, 465.2		262.9, 554.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	242.18 (71.030)	-29.62 (40.436)	340.20 (110.739)	2.20 (20.205)		
	95% CI of Mean	216.12, 268.24	-46.31, -12.92	293.43, 386.96	-8.19, 12.59		
	Median	244.61	-39.99	337.77	2.95		
	Q25, Q75	174.28, 303.84	-45.11, -23.78	277.33, 427.65	-8.34, 17.93		
	Min, Max	102.7, 374.3	-73.9, 144.4	40.5, 548.6	-37.4, 36.1		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	343.00 (103.292)		320.97 (66.907)		367.72 (106.030)	
	95% CI of Mean	302.94, 383.06		293.35, 348.59		286.21, 449.23	
	Median	317.31		302.41		359.24	
	Q25, Q75	265.67, 394.17		275.73, 364.87		290.80, 446.61	
	Min, Max	153.1, 588.1		211.2, 465.2		229.2, 554.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	256.02 (79.609)	-17.59 (45.471)	392.11 (121.875)	12.80 (26.295)		
	95% CI of Mean	222.40, 289.64	-38.87, 3.70	329.44, 454.78	-3.92, 29.51		
	Median	258.88	-23.91	334.91	6.67		
	Q25, Q75	189.72, 336.19	-48.02, -5.51	294.42, 497.14	-0.16, 19.96		
	Min, Max	134.4, 371.3	-66.4, 140.6	269.4, 649.1	-21.2, 81.1		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	352.27 (97.529)		316.68 (67.200)		342.96 (98.947)	
	95% CI of Mean	318.24, 386.31		287.62, 345.75		239.12, 446.81	
	Median	353.60		298.17		325.02	
	Q25, Q75	266.75, 415.24		272.10, 364.87		262.90, 446.61	
	Min, Max	153.1, 588.1		211.2, 465.2		229.2, 469.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total smoking duration (s) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	249.17 (75.246)	-22.04 (37.087)	341.88 (100.445)	6.44 (28.055)		
	95% CI of Mean	224.08, 274.27	-37.02, -7.06	291.92, 391.83	-10.52, 23.40		
	Median	252.07	-26.53	313.25	16.50		
	Q25, Q75	200.38, 303.74	-44.72, -6.82	290.31, 399.93	-13.62, 21.50		
	Min, Max	22.1, 367.6	-94.9, 115.2	201.2, 623.2	-34.7, 51.7		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	2081.89 (1171.501)		1932.69 (1112.530)		1945.85 (1017.034)	
	95% CI of Mean	1765.18, 2398.60		1462.90, 2402.47		1422.94, 2468.77	
	Median	1905.08		1466.15		1447.83	
	Q25, Q75	1204.24, 2460.86		1081.08, 2499.84		1260.93, 2673.24	
	Min, Max	680.9, 6270.0		684.8, 4827.9		695.3, 4314.5	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	2202.28 (1311.935)	22.61 (85.162)	1899.22 (1239.119)	-2.64 (16.258)		
	95% CI of Mean	1847.61, 2556.96	-2.40, 47.62	1375.98, 2422.46	-9.67, 4.40		
	Median	2041.08	-1.60	1574.42	-6.61		
	Q25, Q75	1275.42, 2622.82	-25.47, 50.58	982.46, 2630.66	-10.86, 4.51		
	Min, Max	377.4, 6983.9	-77.8, 341.7	639.5, 5460.4	-33.2, 46.7		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	2343.87 (1191.196)	34.02 (74.584)	2014.15 (1164.244)	4.92 (25.837)		
	95% CI of Mean	2027.80, 2659.94	11.87, 56.18	1533.57, 2494.74	-6.85, 16.68		
	Median	2178.78	10.74	1724.00	4.89		
	Q25, Q75	1630.04, 2793.83	-15.81, 68.62	1122.28, 2497.30	-17.65, 17.92		
	Min, Max	639.7, 7227.0	-52.8, 277.8	846.0, 5710.4	-34.7, 53.5		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	2034.10 (1183.717)		1892.54 (1138.682)		1735.81 (883.095)	
	95% CI of Mean	1583.83, 2484.36		1411.71, 2373.37		1104.07, 2367.54	
	Median	1714.49		1420.71		1741.42	
	Q25, Q75	1088.31, 2524.75		1057.15, 2499.84		834.13, 2316.73	
	Min, Max	680.9, 6151.9		684.8, 4827.9		695.3, 2987.8	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	2416.94 (1245.530)	36.60 (70.954)	1852.02 (1102.074)	6.64 (36.312)		
	95% CI of Mean	1960.07, 2873.81	7.31, 65.89	1386.65, 2317.39	-12.04, 25.31		
	Median	1918.06	18.81	1619.37	-5.51		
	Q25, Q75	1616.68, 3370.03	-13.49, 81.43	1060.79, 2088.81	-21.76, 15.72		
	Min, Max	477.9, 6070.7	-62.8, 276.7	686.8, 5397.6	-33.4, 77.5		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	1995.44 (833.588)		1884.51 (1115.430)		1834.80 (993.284)	
	95% CI of Mean	1672.20, 2318.68		1424.08, 2344.94		1071.29, 2598.31	
	Median	1876.51		1426.28		1307.44	
	Q25, Q75	1405.74, 2603.22		1068.28, 2486.67		1123.32, 2846.28	
	Min, Max	680.9, 3975.6		684.8, 4827.9		739.2, 3219.3	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	2589.42 (1163.430)	50.82 (93.298)	1785.75 (893.702)	-0.46 (28.604)		
	95% CI of Mean	2098.15, 3080.70	7.15, 94.49	1326.24, 2245.25	-18.64, 17.72		
	Median	2250.29	36.14	1742.53	-0.10		
	Q25, Q75	1525.25, 3747.15	-6.77, 65.47	1102.91, 2016.50	-16.12, 22.45		
	Min, Max	1223.4, 4700.1	-62.1, 370.9	803.4, 4297.5	-58.7, 36.1		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	1959.46 (834.852)		1908.11 (1160.367)		2045.58 (1087.984)	
	95% CI of Mean	1668.16, 2250.76		1406.33, 2409.90		903.81, 3187.36	
	Median	1790.93		1426.28		2076.86	
	Q25, Q75	1324.16, 2524.75		1046.02, 2513.02		1173.52, 2987.83	
	Min, Max	680.9, 3975.6		684.8, 4827.9		739.2, 3219.3	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Total work (mJ) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	2533.28 (1282.622)	53.91 (113.558)	1887.64 (1415.744)	7.07 (34.238)		
	95% CI of Mean	2105.62, 2960.93	8.04, 99.78	1183.60, 2591.68	-13.63, 27.76		
	Median	2448.45	26.98	1460.29	6.22		
	Q25, Q75	1358.89, 3489.21	-12.18, 89.11	1081.26, 2083.91	-14.43, 31.33		
	Min, Max	464.3, 5027.3	-57.7, 516.9	502.6, 5618.1	-52.1, 60.3		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	163.12 (86.058)		141.80 (63.790)		145.96 (75.732)	
	95% CI of Mean	139.85, 186.39		114.86, 168.74		107.02, 184.90	
	Median	144.00		127.37		154.98	
	Q25, Q75	107.88, 208.65		90.29, 205.37		85.62, 191.04	
	Min, Max	41.0, 412.5		50.5, 257.9		46.9, 279.4	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	160.57 (107.155)	5.47 (70.334)	135.90 (77.396)	-2.82 (12.991)		
	95% CI of Mean	131.60, 189.54	-15.19, 26.12	103.22, 168.59	-8.44, 2.80		
	Median	149.40	-9.22	110.84	-6.36		
	Q25, Q75	86.99, 191.79	-27.28, 19.64	74.87, 196.93	-11.97, 2.94		
	Min, Max	19.2, 646.8	-82.2, 350.5	53.1, 351.5	-17.4, 36.3		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	165.17 (105.799)	15.71 (64.789)	153.07 (74.210)	6.86 (22.763)		
	95% CI of Mean	137.09, 193.24	-3.54, 34.95	122.44, 183.71	-3.50, 17.23		
	Median	145.49	0.15	132.35	1.26		
	Q25, Q75	100.01, 214.36	-20.60, 31.93	103.32, 193.44	-6.80, 9.89		
	Min, Max	26.1, 710.7	-62.2, 254.5	49.0, 368.2	-26.4, 67.6		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	156.58 (85.447)		138.62 (65.393)		134.43 (76.557)	
	95% CI of Mean	124.07, 189.08		111.01, 166.24		79.66, 189.20	
	Median	139.08		121.93		125.94	
	Q25, Q75	102.13, 208.65		82.56, 205.37		73.05, 169.10	
	Min, Max	41.0, 412.5		50.5, 257.9		46.9, 276.2	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	162.77 (93.333)	17.95 (69.646)	147.71 (80.813)	5.95 (22.588)		
	95% CI of Mean	128.53, 197.01	-10.80, 46.71	113.58, 181.84	-5.67, 17.57		
	Median	132.92	-1.49	124.62	3.22		
	Q25, Q75	97.66, 230.25	-20.00, 27.95	91.43, 180.36	-13.47, 18.03		
	Min, Max	44.1, 449.8	-47.0, 281.6	64.8, 382.9	-25.1, 48.4		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	158.44 (70.541)		138.96 (64.038)		135.09 (86.987)	
	95% CI of Mean	131.08, 185.79		112.52, 165.40		68.22, 201.96	
	Median	147.23		124.36		96.89	
	Q25, Q75	109.42, 216.35		87.76, 197.29		66.53, 217.57	
	Min, Max	41.0, 305.6		50.5, 257.9		46.9, 276.2	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	178.51 (94.064)	30.65 (77.931)	132.72 (65.541)	2.98 (30.651)		
	95% CI of Mean	138.79, 218.23	-5.83, 67.12	99.02, 166.43	-16.50, 22.46		
	Median	144.42	9.27	118.75	3.39		
	Q25, Q75	109.55, 239.48	-14.96, 63.34	84.76, 171.32	-14.70, 11.55		
	Min, Max	34.6, 400.9	-63.6, 285.3	47.7, 307.0	-47.6, 81.4		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	154.54 (70.095)		140.54 (66.632)		156.34 (94.341)	
	95% CI of Mean	130.07, 179.00		111.72, 169.36		57.33, 255.35	
	Median	141.44		130.38		157.23	
	Q25, Q75	108.66, 208.65		77.35, 213.44		73.05, 224.24	
	Min, Max	41.0, 305.6		50.5, 257.9		50.1, 276.2	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Work (mJ) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	167.65 (79.935)	31.45 (104.830)	148.15 (80.622)	15.66 (22.508)		
	95% CI of Mean	141.00, 194.31	-10.90, 73.80	108.05, 188.25	2.06, 29.27		
	Median	157.26	5.88	118.76	15.56		
	Q25, Q75	115.60, 207.89	-18.90, 57.99	93.78, 216.74	10.16, 32.34		
	Min, Max	41.5, 379.0	-58.5, 502.0	35.9, 336.6	-34.7, 41.9		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	281.20 (94.271)		255.72 (124.001)		248.50 (90.275)	
	95% CI of Mean	255.71, 306.69		203.35, 308.08		202.08, 294.92	
	Median	262.76		214.45		219.81	
	Q25, Q75	209.97, 337.26		183.74, 300.63		177.49, 308.34	
	Min, Max	115.3, 585.9		115.3, 638.8		138.0, 412.8	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	236.08 (87.402)	-12.79 (28.418)	251.14 (130.377)	-1.97 (10.049)		
	95% CI of Mean	212.45, 259.72	-21.14, -4.44	196.08, 306.19	-6.32, 2.38		
	Median	211.79	-19.41	226.63	-3.86		
	Q25, Q75	170.40, 284.50	-31.90, 3.96	165.42, 295.16	-9.63, 3.25		
	Min, Max	88.3, 496.8	-66.4, 93.6	107.1, 668.6	-18.3, 22.3		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	234.80 (85.318)	-8.25 (25.480)	271.97 (120.465)	2.08 (12.617)		
	95% CI of Mean	212.16, 257.44	-15.82, -0.67	222.24, 321.70	-3.67, 7.82		
	Median	218.74	-7.95	251.09	1.16		
	Q25, Q75	162.73, 292.92	-24.06, -0.27	209.38, 301.60	-5.10, 8.87		
	Min, Max	70.9, 448.8	-52.3, 72.6	109.3, 695.4	-16.8, 40.0		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	275.82 (105.580)		243.49 (121.872)		230.43 (72.933)	
	95% CI of Mean	235.65, 315.98		192.03, 294.96		178.25, 282.61	
	Median	233.85		212.25		227.22	
	Q25, Q75	209.97, 313.92		169.40, 286.41		177.49, 279.63	
	Min, Max	115.3, 585.9		115.3, 638.8		138.0, 355.4	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	265.34 (88.062)	5.90 (41.402)	235.19 (83.120)	6.51 (18.694)		
	95% CI of Mean	233.04, 297.65	-11.20, 22.99	200.09, 270.29	-3.11, 16.13		
	Median	241.46	-6.29	209.90	4.06		
	Q25, Q75	193.11, 330.83	-23.76, 22.52	177.62, 273.77	-6.39, 9.08		
	Min, Max	153.5, 477.9	-43.9, 104.4	131.2, 431.6	-19.2, 56.2		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	286.01 (108.054)		250.43 (124.240)		257.69 (90.586)	
	95% CI of Mean	244.11, 327.92		199.14, 301.71		188.05, 327.33	
	Median	281.90		212.85		262.52	
	Q25, Q75	210.15, 348.47		180.01, 296.36		187.57, 308.34	
	Min, Max	115.3, 585.9		115.3, 638.8		140.9, 412.8	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	287.17 (113.401)	9.46 (57.935)	228.87 (63.423)	5.27 (16.104)		
	95% CI of Mean	239.28, 335.06	-17.66, 36.58	196.25, 261.48	-4.96, 15.51		
	Median	274.00	-1.37	225.46	0.83		
	Q25, Q75	199.78, 374.14	-29.17, 16.83	195.59, 267.75	-6.13, 9.19		
	Min, Max	134.2, 520.1	-50.2, 159.2	120.7, 334.0	-8.5, 37.9		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	283.03 (104.448)		254.88 (128.711)		286.87 (92.618)	
	95% CI of Mean	246.58, 319.48		199.22, 310.55		189.67, 384.07	
	Median	256.19		216.05		293.98	
	Q25, Q75	210.33, 328.37		158.79, 304.90		187.57, 355.44	
	Min, Max	115.3, 585.9		115.3, 638.8		177.5, 412.8	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	293.76 (106.464)	16.70 (62.654)	272.63 (108.443)	10.84 (17.748)		
	95% CI of Mean	258.26, 329.27	-8.61, 42.01	218.70, 326.56	0.11, 21.57		
	Median	282.02	2.31	257.94	5.06		
	Q25, Q75	214.35, 340.03	-20.85, 23.19	217.04, 289.71	-2.10, 26.33		
	Min, Max	113.4, 534.8	-45.8, 260.0	131.1, 623.8	-16.1, 42.5		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	444.49 (149.454)		404.50 (179.475)		389.62 (143.276)	
	95% CI of Mean	404.08, 484.90		328.71, 480.29		315.95, 463.29	
	Median	404.69		366.25		358.21	
	Q25, Q75	328.80, 580.35		302.70, 499.54		266.83, 497.72	
	Min, Max	181.6, 836.0		174.2, 850.6		201.1, 685.8	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	384.40 (150.018)	-10.75 (29.557)	399.00 (191.893)	-1.35 (9.968)		
	95% CI of Mean	343.84, 424.97	-19.43, -2.07	317.97, 480.04	-5.66, 2.97		
	Median	380.56	-17.50	349.79	-1.45		
	Q25, Q75	268.14, 484.88	-31.43, 5.56	266.61, 505.01	-10.24, 4.80		
	Min, Max	120.0, 804.1	-70.4, 109.2	153.1, 891.5	-17.6, 24.4		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	382.30 (141.040)	-5.63 (28.094)	429.04 (167.036)	2.78 (12.318)		
	95% CI of Mean	344.88, 419.73	-13.98, 2.72	360.08, 497.99	-2.84, 8.39		
	Median	366.97	-6.56	393.25	0.82		
	Q25, Q75	266.68, 450.34	-24.29, 8.06	338.81, 505.78	-4.04, 7.44		
	Min, Max	131.7, 720.3	-52.0, 101.0	153.1, 913.9	-12.6, 41.3		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	433.01 (162.426)		387.65 (177.797)		357.34 (123.471)	
	95% CI of Mean	371.22, 494.80		312.56, 462.73		269.01, 445.67	
	Median	400.50		356.39		359.22	
	Q25, Q75	316.84, 517.77		265.50, 449.49		256.25, 442.96	
	Min, Max	181.6, 836.0		174.2, 850.6		201.1, 567.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	437.87 (155.478)	9.03 (41.934)	376.96 (146.194)	5.26 (17.746)		
	95% CI of Mean	380.84, 494.90	-8.29, 26.34	315.23, 438.70	-3.87, 14.39		
	Median	394.63	-4.15	317.99	6.39		
	Q25, Q75	298.02, 560.81	-17.64, 24.44	279.42, 492.62	-6.82, 10.18		
	Min, Max	237.3, 773.0	-43.2, 116.9	185.4, 696.4	-19.6, 47.7		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	456.25 (164.926)		396.76 (179.915)		392.96 (161.234)	
	95% CI of Mean	392.29, 520.21		322.49, 471.03		269.02, 516.90	
	Median	431.81		361.15		360.24	
	Q25, Q75	340.25, 596.75		291.26, 477.89		266.83, 497.72	
	Min, Max	181.6, 836.0		174.2, 850.6		213.6, 685.8	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	466.44 (191.745)	10.60 (56.991)	369.43 (115.149)	4.54 (16.175)		
	95% CI of Mean	385.47, 547.41	-16.08, 37.28	310.22, 428.64	-5.74, 14.82		
	Median	468.32	-7.09	375.62	-2.89		
	Q25, Q75	304.86, 641.73	-28.04, 23.13	304.12, 470.55	-5.57, 14.10		
	Min, Max	210.6, 822.7	-53.0, 167.5	170.7, 521.9	-10.5, 38.0		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	450.79 (159.322)		401.99 (186.904)		438.98 (173.204)	
	95% CI of Mean	395.20, 506.39		321.16, 482.82		257.21, 620.75	
	Median	401.81		371.35		428.98	
	Q25, Q75	347.49, 592.87		239.74, 521.19		266.83, 567.03	
	Min, Max	181.6, 836.0		174.2, 850.6		256.2, 685.8	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Average Peak pressure drop (mmWg) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	488.17 (171.920)	23.41 (67.430)	419.44 (160.517)	8.90 (17.456)		
	95% CI of Mean	430.84, 545.49	-3.83, 50.65	339.61, 499.27	-1.66, 19.45		
	Median	480.95	11.05	377.46	1.72		
	Q25, Q75	362.13, 603.03	-16.17, 30.15	325.46, 463.80	-6.66, 21.69		
	Min, Max	190.4, 804.3	-50.1, 292.4	198.4, 865.3	-8.5, 44.7		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	2.10 (1.469)		2.19 (0.819)		2.02 (0.862)	
	95% CI of Mean	1.70, 2.50		1.83, 2.54		1.57, 2.47	
	Median	1.69		2.09		2.06	
	Q25, Q75	1.38, 2.29		1.63, 2.57		1.36, 2.56	
	Min, Max	0.7, 10.8		1.0, 4.7		0.8, 3.9	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	3.20 (1.523)	87.72 (115.950)	2.17 (0.848)	1.37 (16.446)		
	95% CI of Mean	2.78, 3.61	53.67, 121.77	1.81, 2.53	-5.75, 8.49		
	Median	2.86	58.53	2.06	4.19		
	Q25, Q75	2.10, 4.09	23.52, 116.62	1.61, 2.66	-10.62, 13.56		
	Min, Max	1.1, 7.0	-86.4, 496.9	0.9, 4.7	-36.8, 32.2		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	3.68 (1.599)	111.90 (116.981)	2.15 (1.063)	6.69 (30.010)		
	95% CI of Mean	3.26, 4.11	77.16, 146.64	1.71, 2.59	-6.97, 20.36		
	Median	3.43	83.13	2.07	1.71		
	Q25, Q75	2.53, 4.64	42.68, 168.23	1.32, 2.57	-14.77, 18.96		
	Min, Max	1.1, 8.7	-89.6, 428.9	0.9, 5.9	-33.5, 93.3		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	2.24 (1.882)		2.20 (0.808)		1.80 (0.792)	
	95% CI of Mean	1.52, 2.96		1.86, 2.55		1.23, 2.38	
	Median	1.69		2.09		1.83	
	Q25, Q75	1.28, 2.18		1.80, 2.57		1.03, 2.56	
	Min, Max	0.9, 10.8		1.0, 4.7		0.8, 3.0	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	3.63 (1.663)	120.59 (119.850)	2.28 (1.105)	-0.02 (30.413)		
	95% CI of Mean	3.02, 4.25	71.11, 170.06	1.81, 2.75	-15.66, 15.62		
	Median	3.35	95.11	2.22	-7.15		
	Q25, Q75	2.16, 4.37	45.57, 206.10	1.42, 2.44	-22.91, 16.87		
	Min, Max	0.8, 7.1	-87.4, 422.2	1.0, 5.8	-37.2, 77.7		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	2.30 (1.867)		2.17 (0.805)		1.88 (0.898)	
	95% CI of Mean	1.57, 3.03		1.83, 2.51		1.19, 2.58	
	Median	1.99		2.07		1.60	
	Q25, Q75	1.44, 2.30		1.80, 2.48		1.30, 2.62	
	Min, Max	1.0, 10.8		1.0, 4.7		0.8, 3.2	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	3.69 (1.787)	130.59 (179.675)	1.95 (0.988)	-14.80 (26.920)		
	95% CI of Mean	2.93, 4.45	46.49, 214.68	1.43, 2.46	-31.91, 2.31		
	Median	3.59	88.67	1.83	-16.20		
	Q25, Q75	2.05, 4.95	11.10, 179.65	1.67, 2.11	-28.74, 4.06		
	Min, Max	1.3, 7.5	-86.1, 624.9	0.7, 5.0	-67.3, 28.7		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	2.16 (1.725)		2.19 (0.836)		2.01 (0.958)	
	95% CI of Mean	1.55, 2.76		1.83, 2.56		1.00, 3.02	
	Median	1.70		2.11		1.87	
	Q25, Q75	1.39, 2.18		1.46, 2.65		1.30, 3.03	
	Min, Max	0.9, 10.8		1.0, 4.7		0.8, 3.2	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Smoking Intensity (mL/s) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	3.44 (1.748)	112.35 (159.244)	2.08 (1.517)	-1.96 (47.727)		
	95% CI of Mean	2.85, 4.02	48.03, 176.68	1.32, 2.83	-30.80, 26.89		
	Median	3.22	67.70	1.57	-6.03		
	Q25, Q75	2.25, 4.38	4.83, 170.70	1.08, 2.94	-32.08, 15.20		
	Min, Max	0.8, 9.1	-85.8, 551.2	0.3, 5.4	-59.4, 128.7		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	6.85 (4.694)		7.50 (2.432)		6.62 (2.122)	
	95% CI of Mean	5.58, 8.12		6.47, 8.53		5.53, 7.72	
	Median	5.85		7.48		6.95	
	Q25, Q75	4.74, 7.62		5.80, 8.34		4.95, 8.06	
	Min, Max	3.3, 37.2		3.4, 12.8		3.6, 10.2	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	11.86 (5.551)	100.25 (101.915)	7.84 (2.800)	6.27 (17.697)		
	95% CI of Mean	10.36, 13.37	70.32, 130.17	6.65, 9.03	-1.39, 13.92		
	Median	10.48	72.93	7.93	3.31		
	Q25, Q75	6.73, 16.11	30.18, 161.94	5.28, 9.71	-4.69, 16.31		
	Min, Max	3.5, 23.6	-85.3, 451.6	3.4, 12.6	-20.0, 53.1		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set**

Parameter: Puffing Time Index (%) (average over visit)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	14.00 (6.362)	125.21 (108.914)	7.13 (3.257)	7.49 (36.810)		
	95% CI of Mean	12.31, 15.70	92.86, 157.56	5.78, 8.48	-9.27, 24.25		
	Median	13.27	107.37	7.09	0.35		
	Q25, Q75	8.87, 18.33	53.96, 195.05	4.82, 9.54	-10.38, 20.51		
	Min, Max	4.5, 30.6	-87.6, 491.1	2.4, 14.9	-33.8, 143.9		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	7.37 (6.158)		7.66 (2.330)		6.20 (2.082)	
	95% CI of Mean	5.02, 9.71		6.67, 8.65		4.71, 7.70	
	Median	5.88		7.60		5.94	
	Q25, Q75	4.93, 7.33		6.32, 8.34		4.78, 7.90	
	Min, Max	3.3, 37.2		3.4, 12.8		3.6, 10.2	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	13.76 (6.907)	132.14 (106.775)	7.82 (3.659)	-4.70 (28.685)		
	95% CI of Mean	11.22, 16.30	88.06, 176.21	6.27, 9.37	-19.45, 10.05		
	Median	12.98	123.33	6.27	-6.96		
	Q25, Q75	7.92, 19.29	65.23, 195.24	5.45, 10.21	-21.08, 3.95		
	Min, Max	3.2, 31.7	-84.5, 343.9	2.6, 16.6	-48.5, 70.4		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	7.64 (6.208)		7.52 (2.384)		5.99 (1.483)	
	95% CI of Mean	5.23, 10.05		6.53, 8.51		4.85, 7.14	
	Median	6.10		7.51		5.66	
	Q25, Q75	5.05, 7.68		6.15, 8.29		4.95, 6.95	
	Min, Max	3.8, 37.2		3.4, 12.8		3.7, 8.1	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set**

Parameter: Puffing Time Index (%) (average over visit)
Product Use Time Period: Period 3

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	14.17 (8.767)	127.12 (177.322)	6.94 (3.762)	-10.70 (25.718)		
	95% CI of Mean	10.47, 17.88	44.13, 210.11	5.00, 8.87	-27.04, 5.65		
	Median	11.16	100.32	6.50	-10.62		
	Q25, Q75	7.56, 18.43	44.25, 160.23	4.61, 8.15	-28.16, 11.24		
	Min, Max	3.9, 41.3	-83.3, 802.4	1.5, 14.7	-61.2, 26.2		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puffing Time Index (%) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	7.21 (5.734)		7.40 (2.437)		6.20 (1.176)	
	95% CI of Mean	5.21, 9.22		6.34, 8.46		4.96, 7.43	
	Median	5.87		7.44		6.15	
	Q25, Q75	4.93, 7.62		5.45, 8.29		5.23, 6.95	
	Min, Max	3.3, 37.2		3.4, 12.8		4.8, 7.9	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set**

Parameter: Puffing Time Index (%) (average over visit)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	14.07 (6.500)	122.65 (126.761)	6.33 (4.619)	-8.45 (39.626)		
	95% CI of Mean	11.90, 16.24	71.45, 173.86	4.03, 8.63	-32.40, 15.50		
	Median	13.73	101.06	5.60	-13.84		
	Q25, Q75	9.43, 17.92	57.60, 175.65	3.35, 6.95	-33.98, 13.88		
	Min, Max	3.3, 28.5	-83.9, 439.4	0.7, 20.4	-55.3, 89.8		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	55		24		17	
	Missing, n(%)	20 (26.7)		11 (31.4)		7 (29.2)	
	Mean (SD)	2.64 (1.834)		2.68 (0.701)		2.44 (0.727)	
	95% CI of Mean	2.14, 3.14		2.38, 2.99		2.06, 2.81	
	Median	2.22		2.63		2.38	
	Q25, Q75	1.92, 2.88		2.22, 2.81		1.94, 2.77	
	Min, Max	1.2, 14.7		1.4, 4.4		1.1, 4.2	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 1	n	55	47	24	23		
	Missing, n(%)	20 (26.7)	28 (37.3)	11 (31.4)	12 (34.3)		
	Mean (SD)	3.52 (1.254)	54.34 (47.449)	2.75 (0.676)	1.78 (13.505)		
	95% CI of Mean	3.18, 3.87	40.41, 68.28	2.46, 3.04	-4.07, 7.62		
	Median	3.38	51.20	2.71	1.97		
	Q25, Q75	2.65, 3.97	19.71, 82.98	2.25, 3.12	-6.29, 9.91		
	Min, Max	1.6, 6.9	-86.3, 165.7	1.4, 4.7	-27.8, 30.5		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 4	n	57	46	25	21		
	Missing, n(%)	18 (24.0)	29 (38.7)	10 (28.6)	14 (40.0)		
	Mean (SD)	3.84 (1.517)	66.13 (58.465)	2.64 (0.880)	2.86 (25.878)		
	95% CI of Mean	3.43, 4.25	48.77, 83.50	2.27, 3.01	-8.93, 14.64		
	Median	3.55	59.35	2.56	-2.34		
	Q25, Q75	2.70, 4.55	24.74, 93.65	2.07, 2.98	-12.56, 16.15		
	Min, Max	1.6, 8.5	-88.9, 201.4	1.2, 4.4	-34.7, 69.5		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	29		24		10	
	Missing, n(%)	11 (27.5)		10 (29.4)		3 (23.1)	
	Mean (SD)	2.88 (2.417)		2.69 (0.702)		2.22 (0.568)	
	95% CI of Mean	1.96, 3.81		2.39, 2.99		1.81, 2.63	
	Median	2.29		2.63		2.28	
	Q25, Q75	2.14, 2.99		2.22, 2.83		1.88, 2.77	
	Min, Max	1.2, 14.7		1.4, 4.4		1.1, 2.9	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 2**

Timepoint	Statistic	THSm2.2 (N=40)		mCC (N=34)		SA (N=13)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 30	n	31	25	24	17		
	Missing, n(%)	9 (22.5)	15 (37.5)	10 (29.4)	17 (50.0)		
	Mean (SD)	4.33 (1.546)	89.55 (73.133)	2.52 (0.891)	-1.32 (26.533)		
	95% CI of Mean	3.75, 4.90	59.36, 119.74	2.14, 2.90	-14.97, 12.33		
	Median	4.42	73.41	2.33	-11.96		
	Q25, Q75	2.89, 5.53	36.64, 139.01	1.97, 3.11	-19.43, 17.57		
	Min, Max	1.8, 7.0	-88.0, 248.7	1.2, 4.4	-31.8, 59.2		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	28		25		9	
	Missing, n(%)	11 (28.2)		10 (28.6)		3 (25.0)	
	Mean (SD)	3.02 (2.465)		2.69 (0.687)		2.59 (0.759)	
	95% CI of Mean	2.06, 3.98		2.40, 2.98		2.01, 3.18	
	Median	2.32		2.67		2.70	
	Q25, Q75	2.16, 3.25		2.22, 2.82		1.94, 2.86	
	Min, Max	1.2, 14.7		1.4, 4.4		1.8, 4.2	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 3**

Timepoint	Statistic	THSm2.2 (N=39)		mCC (N=35)		SA (N=12)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 60	n	24	20	17	12		
	Missing, n(%)	15 (38.5)	19 (48.7)	18 (51.4)	23 (65.7)		
	Mean (SD)	4.09 (1.670)	66.05 (89.537)	2.29 (0.640)	-12.93 (20.238)		
	95% CI of Mean	3.38, 4.80	24.14, 107.96	1.96, 2.63	-25.80, -0.07		
	Median	4.07	52.06	2.05	-12.93		
	Q25, Q75	2.54, 5.21	12.79, 99.44	1.94, 2.92	-21.73, -4.62		
	Min, Max	1.7, 7.9	-87.5, 341.5	1.3, 3.3	-59.7, 19.4		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	34		23		6	
	Missing, n(%)	13 (27.7)		9 (28.1)		3 (33.3)	
	Mean (SD)	2.86 (2.263)		2.73 (0.704)		2.66 (0.908)	
	95% CI of Mean	2.06, 3.65		2.42, 3.04		1.70, 3.61	
	Median	2.30		2.68		2.53	
	Q25, Q75	1.81, 3.16		2.22, 2.84		1.88, 2.93	
	Min, Max	1.2, 14.7		1.4, 4.4		1.8, 4.2	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.60 Descriptive Statistics of HST Parameters per Cigarette - PP Set****Parameter: Puff Frequency (puffs/min) (average over visit)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	37	26	18	13		
	Missing, n(%)	10 (21.3)	21 (44.7)	14 (43.8)	19 (59.4)		
	Mean (SD)	4.34 (2.350)	86.16 (134.924)	2.42 (1.129)	-11.08 (31.075)		
	95% CI of Mean	3.55, 5.13	31.66, 140.66	1.85, 2.99	-29.87, 7.70		
	Median	4.02	49.05	2.28	-16.09		
	Q25, Q75	2.83, 5.09	27.90, 103.74	1.49, 2.90	-33.53, 4.02		
	Min, Max	1.8, 13.6	-87.1, 647.3	0.9, 5.3	-46.5, 66.0		

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Total number of puffs (average over visit)				
Day 1	n	47	23	
	LS Mean	14.74	13.52	1.22
	95% CI	13.86, 15.62	12.24, 14.79	-0.30, 2.75
Day 4	n	46	21	
	LS Mean	15.22	13.35	1.88
	95% CI	14.43, 16.02	12.14, 14.56	0.45, 3.30

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Total number of puffs (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	15.82	13.84	1.98
	95% CI	14.12, 17.52	11.84, 15.83	-0.67, 4.63
Day 60	n	20	12	
	LS Mean	16.17	13.16	3.01
	95% CI	14.25, 18.09	10.71, 15.61	-0.26, 6.28
Day 90	n	26	13	
	LS Mean	15.73	12.40	3.34
	95% CI	13.75, 17.72	9.71, 15.08	-0.13, 6.81

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Total puff volume (mL) (average over visit)				
Day 1	n	47	23	
	LS Mean	779.95	653.65	126.30
	95% CI	687.91, 872.00	521.40, 785.91	-32.72, 285.31
Day 4	n	46	21	
	LS Mean	868.42	680.90	187.51
	95% CI	779.04, 957.79	546.33, 815.48	28.11, 346.91

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Total puff volume (mL) (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	827.33	716.77	110.56
	95% CI	708.05, 946.60	575.51, 858.02	-77.63, 298.75
Day 60	n	20	12	
	LS Mean	873.76	671.45	202.30
	95% CI	708.12, 1039.40	459.76, 883.15	-88.71, 493.31
Day 90	n	26	13	
	LS Mean	792.98	623.15	169.84
	95% CI	655.86, 930.10	437.77, 808.52	-69.94, 409.61

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Average puff volume (mL) (average over visit)				
Day 1	n	47	23	
	LS Mean	55.93	48.56	7.37
	95% CI	50.74, 61.13	41.10, 56.02	-1.57, 16.31
Day 4	n	46	21	
	LS Mean	60.19	51.85	8.35
	95% CI	53.96, 66.43	42.48, 61.22	-2.74, 19.44

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.7.1

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Average puff volume (mL) (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	54.51	51.36	3.15
	95% CI	48.66, 60.36	44.48, 58.23	-6.06, 12.36
Day 60	n	20	12	
	LS Mean	59.26	49.96	9.30
	95% CI	47.32, 71.20	35.15, 64.77	-11.03, 29.64
Day 90	n	26	13	
	LS Mean	51.27	51.39	-0.12
	95% CI	44.84, 57.69	42.74, 60.04	-11.29, 11.05

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Average puff duration (s) (average over visit)				
Day 1	n	47	23	
	LS Mean	2.09	1.75	0.35
	95% CI	1.94, 2.25	1.53, 1.96	0.09, 0.61
Day 4	n	46	21	
	LS Mean	2.19	1.70	0.49
	95% CI	2.03, 2.34	1.47, 1.92	0.22, 0.75

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Average puff duration (s) (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	2.11	1.69	0.42
	95% CI	1.88, 2.33	1.43, 1.95	0.06, 0.78
Day 60	n	20	12	
	LS Mean	2.17	1.73	0.44
	95% CI	1.89, 2.44	1.40, 2.07	-0.02, 0.90
Day 90	n	26	13	
	LS Mean	1.98	1.67	0.32
	95% CI	1.75, 2.21	1.36, 1.97	-0.08, 0.71

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Total puff duration (s) (average over visit)				
Day 1	n	47	23	
	LS Mean	30.11	22.23	7.88
	95% CI	27.20, 33.01	18.03, 26.43	2.78, 12.98
Day 4	n	46	21	
	LS Mean	32.29	21.17	11.12
	95% CI	29.19, 35.39	16.48, 25.86	5.55, 16.69

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Total puff duration (s) (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	31.19	23.14	8.05
	95% CI	26.84, 35.54	17.97, 28.32	0.93, 15.17
Day 60	n	20	12	
	LS Mean	33.82	21.16	12.67
	95% CI	28.23, 39.42	14.01, 28.30	2.76, 22.58
Day 90	n	26	13	
	LS Mean	31.92	19.13	12.79
	95% CI	26.25, 37.59	11.51, 26.74	2.94, 22.64

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Average flow (mL/s) (average over visit)				
Day 1	n	47	23	
	LS Mean	28.86	30.84	-1.98
	95% CI	26.76, 30.97	27.82, 33.87	-5.62, 1.66
Day 4	n	46	21	
	LS Mean	30.12	33.21	-3.09
	95% CI	28.08, 32.16	30.15, 36.27	-6.72, 0.54

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Average flow (mL/s) (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	29.63	31.89	-2.26
	95% CI	26.45, 32.81	28.18, 35.59	-7.26, 2.74
Day 60	n	20	12	
	LS Mean	30.78	30.45	0.33
	95% CI	25.43, 36.13	23.80, 37.10	-8.62, 9.29
Day 90	n	26	13	
	LS Mean	28.08	35.49	-7.41
	95% CI	24.78, 31.38	31.04, 39.94	-13.18, -1.65

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Average Peak flow (mL/s) (average over visit)				
Day 1	n	47	23	
	LS Mean	43.55	46.51	-2.96
	95% CI	40.45, 46.64	42.06, 50.96	-8.31, 2.38
Day 4	n	46	21	
	LS Mean	45.07	49.80	-4.74
	95% CI	42.06, 48.07	45.28, 54.32	-10.09, 0.61

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Average Peak flow (mL/s) (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	44.91	47.75	-2.85
	95% CI	40.02, 49.80	42.04, 53.47	-10.51, 4.82
Day 60	n	20	12	
	LS Mean	44.97	45.57	-0.60
	95% CI	37.72, 52.22	36.56, 54.59	-12.74, 11.54
Day 90	n	26	13	
	LS Mean	43.13	52.05	-8.93
	95% CI	38.27, 47.98	45.52, 58.59	-17.38, -0.48

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Total inter puff interval (s) (average over visit)				
Day 1	n	47	23	
	LS Mean	238.51	299.68	-61.17
	95% CI	221.70, 255.33	275.64, 323.73	-90.48, -31.86
Day 4	n	46	21	
	LS Mean	225.73	300.25	-74.52
	95% CI	206.02, 245.43	270.71, 329.79	-109.87, -39.18

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Total inter puff interval (s) (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	207.21	321.39	-114.18
	95% CI	173.99, 240.42	282.15, 360.62	-166.43, -61.92
Day 60	n	20	12	
	LS Mean	232.43	351.70	-119.27
	95% CI	182.52, 282.33	289.85, 413.55	-203.06, -35.49
Day 90	n	26	13	
	LS Mean	210.84	313.71	-102.87
	95% CI	177.39, 244.28	268.46, 358.96	-161.24, -44.50

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Average inter puff interval (s) (average over visit)				
Day 1	n	47	23	
	LS Mean	17.44	23.76	-6.32
	95% CI	15.76, 19.11	21.31, 26.21	-9.29, -3.35
Day 4	n	46	21	
	LS Mean	15.62	24.34	-8.72
	95% CI	13.63, 17.60	21.30, 27.38	-12.34, -5.11

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Average inter puff interval (s) (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	13.96	24.68	-10.72
	95% CI	11.02, 16.90	21.19, 28.16	-15.33, -6.11
Day 60	n	20	12	
	LS Mean	15.96	26.46	-10.50
	95% CI	12.02, 19.89	21.59, 31.32	-17.05, -3.94
Day 90	n	26	13	
	LS Mean	15.80	29.07	-13.27
	95% CI	11.36, 20.24	23.06, 35.08	-21.02, -5.52

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Total smoking duration (s) (average over visit)				
Day 1	n	47	23	
	LS Mean	267.86	323.38	-55.52
	95% CI	250.88, 284.84	299.10, 347.66	-85.03, -26.02
Day 4	n	46	21	
	LS Mean	257.38	322.92	-65.54
	95% CI	237.88, 276.87	293.71, 352.12	-100.43, -30.65

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Total smoking duration (s) (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	237.71	345.36	-107.65
	95% CI	204.53, 270.88	306.26, 384.46	-159.70, -55.61
Day 60	n	20	12	
	LS Mean	264.15	375.94	-111.80
	95% CI	216.05, 312.24	316.32, 435.56	-192.72, -30.87
Day 90	n	26	13	
	LS Mean	243.31	331.93	-88.62
	95% CI	209.94, 276.68	286.78, 377.08	-146.88, -30.36

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Total work (mJ) (average over visit)				
Day 1	n	47	23	
	LS Mean	2134.95	1958.23	176.72
	95% CI	1810.58, 2459.31	1491.62, 2424.84	-383.58, 737.01
Day 4	n	46	21	
	LS Mean	2409.04	2115.55	293.49
	95% CI	2112.82, 2705.27	1669.99, 2561.11	-234.17, 821.15

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Total work (mJ) (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	2418.31	1993.89	424.43
	95% CI	2061.52, 2775.10	1575.80, 2411.98	-135.68, 984.53
Day 60	n	20	12	
	LS Mean	2674.32	1784.83	889.49
	95% CI	2211.69, 3136.94	1209.58, 2360.08	114.83, 1664.14
Day 90	n	26	13	
	LS Mean	2587.96	2146.32	441.64
	95% CI	2096.81, 3079.11	1485.66, 2806.97	-412.42, 1295.70

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Average Work (mJ) (average over visit)				
Day 1	n	47	23	
	LS Mean	153.31	154.92	-1.61
	95% CI	135.40, 171.22	128.82, 181.03	-32.92, 29.70
Day 4	n	46	21	
	LS Mean	168.41	168.07	0.34
	95% CI	147.85, 188.98	136.88, 199.27	-36.55, 37.23

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Average Work (mJ) (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	158.85	150.53	8.32
	95% CI	134.49, 183.21	121.77, 179.29	-30.33, 46.96
Day 60	n	20	12	
	LS Mean	175.38	147.88	27.49
	95% CI	140.69, 210.07	104.38, 191.38	-31.12, 86.11
Day 90	n	26	13	
	LS Mean	167.59	173.40	-5.81
	95% CI	141.54, 193.63	138.29, 208.51	-51.25, 39.63

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Average pressure drop (mmWg) (average over visit)				
Day 1	n	47	23	
	LS Mean	226.96	263.28	-36.32
	95% CI	209.32, 244.59	237.91, 288.64	-66.83, -5.80
Day 4	n	46	21	
	LS Mean	245.91	278.23	-32.32
	95% CI	230.31, 261.51	254.76, 301.70	-60.12, -4.52

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Average pressure drop (mmWg) (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	262.49	233.83	28.66
	95% CI	230.42, 294.56	195.78, 271.88	-23.66, 80.98
Day 60	n	20	12	
	LS Mean	287.28	236.95	50.33
	95% CI	240.16, 334.40	177.02, 296.88	-32.12, 132.79
Day 90	n	26	13	
	LS Mean	292.79	295.40	-2.62
	95% CI	256.60, 328.98	246.74, 344.07	-65.49, 60.26

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Average Peak pressure drop (mmWg) (average over visit)				
Day 1	n	47	23	
	LS Mean	370.63	422.67	-52.04
	95% CI	342.43, 398.82	382.03, 463.31	-100.91, -3.17
Day 4	n	46	21	
	LS Mean	398.53	443.71	-45.17
	95% CI	373.42, 423.64	405.91, 481.50	-89.93, -0.42

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Average Peak pressure drop (mmWg) (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	427.53	385.68	41.85
	95% CI	375.93, 479.13	324.71, 446.65	-41.53, 125.23
Day 60	n	20	12	
	LS Mean	462.69	394.71	67.98
	95% CI	385.52, 539.86	296.49, 492.93	-66.72, 202.68
Day 90	n	26	13	
	LS Mean	489.86	464.38	25.48
	95% CI	430.01, 549.71	383.72, 545.04	-78.73, 129.68

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Smoking Intensity (mL/s) (average over visit)				
Day 1	n	47	23	
	LS Mean	3.13	2.12	1.01
	95% CI	2.71, 3.55	1.52, 2.72	0.29, 1.73
Day 4	n	46	21	
	LS Mean	3.63	2.26	1.37
	95% CI	3.18, 4.08	1.58, 2.93	0.57, 2.17

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Smoking Intensity (mL/s) (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	3.81	2.20	1.61
	95% CI	3.20, 4.42	1.49, 2.92	0.66, 2.56
Day 60	n	20	12	
	LS Mean	3.73	2.11	1.62
	95% CI	2.89, 4.58	1.06, 3.16	0.20, 3.04
Day 90	n	26	13	
	LS Mean	3.62	2.17	1.46
	95% CI	2.81, 4.44	1.07, 3.26	0.04, 2.87

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Puffing Time Index (%) (average over visit)				
Day 1	n	47	23	
	LS Mean	11.61	7.81	3.80
	95% CI	10.12, 13.10	5.68, 9.93	1.25, 6.36
Day 4	n	46	21	
	LS Mean	13.26	7.63	5.63
	95% CI	11.54, 14.98	5.05, 10.21	2.57, 8.68

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.7.1

Study ID: ZRHM-REXA-08-US

Program: t_anl_hst.sas

Status: Final

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Puffing Time Index (%) (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	13.91	7.86	6.05
	95% CI	11.43, 16.39	4.94, 10.77	2.17, 9.93
Day 60	n	20	12	
	LS Mean	14.04	7.50	6.53
	95% CI	10.10, 17.97	2.61, 12.40	-0.08, 13.14
Day 90	n	26	13	
	LS Mean	14.54	6.19	8.34
	95% CI	11.61, 17.46	2.26, 10.13	3.22, 13.46

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Puff Frequency (puffs/min) (average over visit)				
Day 1	n	47	23	
	LS Mean	3.53	2.79	0.73
	95% CI	3.22, 3.84	2.35, 3.24	0.20, 1.26
Day 4	n	46	21	
	LS Mean	3.89	2.84	1.04
	95% CI	3.52, 4.25	2.29, 3.40	0.39, 1.69

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Appendix 15.3.7.1

Study ID: ZRHM-REXA-08-US

Program: t_anl_hst.sas

Status: Final

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**Table 15.2.4.61 Analysis of HST Parameters per Cigarette - PP Set**

Variable	Statistic	THSm2.2	mCC	THSm2.2 - mCC Difference
Puff Frequency (puffs/min) (average over visit) (cont...)				
Day 30	n	25	17	
	LS Mean	4.50	2.57	1.93
	95% CI	3.99, 5.02	1.97, 3.17	1.12, 2.74
Day 60	n	20	12	
	LS Mean	4.24	2.39	1.85
	95% CI	3.52, 4.97	1.50, 3.29	0.63, 3.07
Day 90	n	26	13	
	LS Mean	4.56	2.33	2.22
	95% CI	3.59, 5.52	1.04, 3.63	0.55, 3.90

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC = Menthol conventional cigarettes; THSm2.2 = Tobacco Heating System 2.2 Menthol.

**Table 15.2.4.62.1 Descriptive Statistics of CYP2A6 Activity (%) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		35		23	
	Missing, n(%)	1 (1.3)		0		1 (4.2)	
	Geometric Mean (CV%)	29.916 (40.1630)		30.071 (35.7472)		28.021 (30.2735)	
	95% CI of Geometric Mean	27.352, 32.721		26.693, 33.875		24.652, 31.849	
	Median	30.525		31.340		28.910	
	Q25, Q75	22.500, 36.940		24.430, 41.040		23.660, 32.800	
	Min, Max	14.14, 69.66		12.61, 60.39		13.32, 65.22	
	Mean (SD)	32.251 (13.1236)		31.785 (10.4456)		29.272 (9.6946)	
	95% CI of Mean	29.210, 35.292		28.196, 35.374		25.079, 33.465	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.62.1 Descriptive Statistics of CYP2A6 Activity (%) - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	74	74	35	35	23	23
	Missing, n(%)	1 (1.3)	1 (1.3)	0	0	1 (4.2)	1 (4.2)
	BLOQ, n (%)	0		0		2 (8.7)	
	Geometric Mean (CV%)	32.633 (38.5332)		31.256 (35.2697)		72.812 (52.9688)	
	95% CI of Geometric Mean	29.938, 35.572		27.787, 35.157		58.723, 90.281	
	Median	35.310	8.529	32.550	0.941	77.380	157.591
	Q25, Q75	25.030, 40.760	-8.460, 22.779	26.000, 37.820	-14.211, 17.636	52.380, 91.670	84.238, 219.949
	Min, Max	16.54, 98.21	-31.72, 124.00	14.67, 60.39	-31.80, 91.80	32.32, 211.21	43.27, 486.11
	Mean (SD)	34.995 (13.9813)	12.504 (29.7513)	32.972 (10.5677)	6.809 (26.4420)	82.665 (47.5486)	180.452 (120.6736)
	95% CI of Mean	31.755, 38.234	5.611, 19.398	29.342, 36.603	-2.275, 15.892	62.103, 103.227	128.269, 232.636

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.62.1 Descriptive Statistics of CYP2A6 Activity (%) - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Geometric Mean (CV%)	28.680 (40.5403)		30.113 (33.5401)		26.244 (30.0416)	
	95% CI of Geometric Mean	25.576, 32.161		26.768, 33.875		20.936, 32.898	
	Median	30.160		31.395		28.560	
	Q25, Q75	20.800, 34.430		25.575, 39.270		26.880, 30.610	
	Min, Max	14.14, 69.66		12.61, 48.65		13.32, 36.01	
	Mean (SD)	30.985 (13.1586)		31.574 (9.2319)		27.140 (6.5827)	
	95% CI of Mean	27.121, 34.849		28.245, 34.903		22.080, 32.200	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.62.1 Descriptive Statistics of CYP2A6 Activity (%) - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	47	32	32	9	9
	BLOQ, n (%)	0		0		2 (22.2)	
	Geometric Mean (CV%)	30.459 (41.5404)		33.183 (31.9735)		44.634 (43.9936)	
	95% CI of Geometric Mean	27.091, 34.245		29.652, 37.134		32.303, 61.671	
	Median	31.400	3.967	35.795	11.270	38.020	38.550
	Q25, Q75	22.410, 41.000	-13.430, 25.834	29.635, 41.225	-6.999, 30.135	36.040, 40.930	24.208, 52.269
	Min, Max	13.02, 63.91	-31.13, 174.06	13.74, 52.92	-34.74, 98.11	28.86, 91.67	0.08, 588.21
	Mean (SD)	32.832 (12.6170)	10.905 (37.6735)	34.637 (9.5736)	13.261 (27.5103)	48.797 (24.5626)	110.910 (188.9485)
	95% CI of Mean	29.127, 36.537	-0.157, 21.967	31.184, 38.089	3.342, 23.180	29.916, 67.678	-34.329, 256.149

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.62.1.1 Descriptive Statistics of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		34		23	
	Missing, n(%)	5 (6.7)		1 (2.9)		1 (4.2)	
	Geometric Mean (CV%)	29.386 (39.1170)		29.460 (33.8919)		28.021 (30.2735)	
	95% CI of Geometric Mean	26.857, 32.153		26.258, 33.053		24.652, 31.849	
	Median	30.525		30.975		28.910	
	Q25, Q75	21.890, 36.470		24.430, 37.500		23.660, 32.800	
	Min, Max	14.14, 69.66		12.61, 48.65		13.32, 65.22	
	Mean (SD)	31.554 (12.4779)		30.944 (9.3216)		29.272 (9.6946)	
	95% CI of Mean	28.579, 34.530		27.691, 34.197		25.079, 33.465	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.62.1.1 Descriptive Statistics of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	70	70	34	34	23	23
	Missing, n(%)	5 (6.7)	5 (6.7)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	BLOQ, n (%)	0		0		2 (8.7)	
	Geometric Mean (CV%)	31.879 (35.3229)		30.656 (33.6498)		72.812 (52.9688)	
	95% CI of Geometric Mean	29.376, 34.595		27.345, 34.368		58.723, 90.281	
	Median	35.130	7.805	32.280	3.036	77.380	157.591
	Q25, Q75	25.030, 39.950	-8.460, 22.111	26.000, 36.240	-14.211, 17.636	52.380, 91.670	84.238, 219.949
	Min, Max Mean (SD)	16.54, 64.07 33.728 (11.2341)	-31.72, 124.00 11.934 (29.9666)	14.67, 58.71 32.166 (9.5714)	-31.80, 91.80 7.009 (26.8127)	32.32, 211.21 82.665 (47.5486)	43.27, 486.11 180.452 (120.6736)

**Table 15.2.4.62.1.1 Descriptive Statistics of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - PP Set****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
	95% CI of Mean	31.049, 36.407	4.788, 19.080	28.826, 35.506	-2.347, 16.365	62.103, 103.227	128.269, 232.636

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.62.1.1 Descriptive Statistics of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	46		32		9	
	Missing, n(%)	1 (2.1)		0		0	
	Geometric Mean (CV%)	28.690 (41.0231)		30.113 (33.5401)		26.244 (30.0416)	
	95% CI of Geometric Mean	25.519, 32.255		26.768, 33.875		20.936, 32.898	
	Median	30.525		31.395		28.560	
	Q25, Q75	20.800, 34.430		25.575, 39.270		26.880, 30.610	
	Min, Max	14.14, 69.66		12.61, 48.65		13.32, 36.01	
	Mean (SD)	31.044 (13.2976)		31.574 (9.2319)		27.140 (6.5827)	
	95% CI of Mean	27.095, 34.994		28.245, 34.903		22.080, 32.200	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.62.1.1 Descriptive Statistics of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - PP Set****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	45	45	32	32	8	8
	Missing, n(%)	2 (4.3)	2 (4.3)	0	0	1 (11.1)	1 (11.1)
	BLOQ, n (%)	0		0		2 (25.0)	
	Geometric Mean (CV%)	29.884 (40.6986)		33.183 (31.9735)		46.057 (46.0160)	
	95% CI of Geometric Mean	26.568, 33.615		29.652, 37.134		31.928, 66.439	
	Median	31.190	3.651	35.795	11.270	39.275	40.231
	Q25, Q75	22.410, 39.180	-13.430, 15.299	29.635, 41.225	-6.999, 30.135	36.385, 66.300	21.231, 129.378
	Min, Max	13.02, 59.68	-31.13, 123.56	13.74, 52.92	-34.74, 98.11	28.86, 91.67	0.08, 588.21
	Mean (SD)	32.111 (11.9959)	7.055 (29.3487)	34.637 (9.5736)	13.261 (27.5103)	50.556 (25.6450)	121.247 (199.2553)
	95% CI of Mean	28.507, 35.716	-1.763, 15.872	31.184, 38.089	3.342, 23.180	29.116, 71.996	-45.335, 287.829

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.62.2 Descriptive Statistics of CYP2A6 Activity (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	%Change(*)	Value	%Change(*)	Value	%Change(*)
Baseline	n	78		41		38	
	Missing, n (%)	2 (2.5)		0		1 (2.6)	
	Geometric Mean (CV%)	29.663 (39.7280)		30.561 (36.1267)		28.619 (33.9086)	
	95% CI of Geometric Mean	27.210, 32.338		27.362, 34.134		25.678, 31.897	
	Median	30.100		31.340		29.185	
	Q25, Q75	21.890, 36.940		24.430, 41.770		24.240, 34.360	
	Min, Max	14.14, 69.66		12.61, 60.39		13.32, 65.22	
	Mean (SD)	31.943 (12.9538)		32.368 (10.8922)		30.146 (10.0506)	
	95% CI of Mean	29.021, 34.864		28.929, 35.806		26.842, 33.450	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n)

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.62.2 Descriptive Statistics of CYP2A6 Activity (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	%Change(*)	Value	%Change(*)	Value	%Change(*)
Day 6/Discharge Confinement	n	78	78	41	41	38	38
	Missing, n (%)	2 (2.5)	2 (2.5)	0	0	1 (2.6)	1 (2.6)
	BLOQ, n (%)	0		0		4 (10.5)	
	Geometric Mean (CV%)	32.265 (38.2700)		31.646 (34.1440)		68.665 (76.0970)	
	95% CI of Geometric Mean	29.685, 35.071		28.496, 35.143		54.985, 85.747	
	Median	35.130	7.805	32.550	0.000	77.725	151.293
	Q25, Q75	25.030, 39.950	-8.460, 22.779	29.310, 37.820	-10.143, 17.636	39.530, 109.720	69.846, 222.024
	Min, Max	16.54, 98.21	-31.72, 124.00	14.67, 60.39	-31.80, 91.80	15.97, 315.33	0.00, 727.42
	Mean (SD)	34.581 (13.8111)	12.075 (29.2140)	33.284 (10.3284)	6.316 (25.8152)	85.401 (61.0198)	176.784 (158.5435)
	95% CI of Mean	31.467, 37.696	5.488, 18.663	30.024, 36.545	-1.833, 14.465	65.343, 105.458	124.671, 228.896

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n)

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.62.2 Descriptive Statistics of CYP2A6 Activity (%) - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	%Change(*)	Value	%Change(*)	Value	%Change(*)
Day 90	n	78	78	41	41	38	38
	Missing, n (%)	2 (2.5)	2 (2.5)	0	0	1 (2.6)	1 (2.6)
	BLOQ, n (%)	0		0		3 (7.9)	
	Geometric Mean (CV%)	32.073 (41.7941)		33.728 (33.4105)		39.481 (41.0039)	
	95% CI of Geometric Mean	29.298, 35.110		30.436, 37.376		34.683, 44.944	
	Median	31.595	6.942	35.990	11.073	38.325	30.945
	Q25, Q75	23.660, 42.470	-9.798, 29.718	29.520, 40.650	-6.334, 26.606	30.330, 45.880	1.872, 52.269
	Min, Max	13.02, 94.02	-31.13, 174.06	13.74, 64.17	-34.74, 98.11	18.17, 91.67	-11.88, 588.21
	Mean (SD)	34.740 (14.6025)	11.853 (32.2199)	35.419 (10.9189)	13.420 (27.4751)	42.792 (19.0919)	52.527 (100.3118)
	95% CI of Mean	31.447, 38.033	4.588, 19.118	31.972, 38.865	4.747, 22.093	36.516, 49.068	19.554, 85.499

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n)

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.62.2.1 Descriptive Statistics of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	%Change(*)	Value	%Change(*)	Value	%Change(*)
Baseline	n	74		40		34	
	Missing, n (%)	6 (7.5)		1 (2.4)		5 (12.8)	
	Geometric Mean (CV%)	29.152 (38.6636)		30.045 (34.6890)		28.227 (34.4387)	
	95% CI of Geometric Mean	26.737, 31.786		26.974, 33.465		25.115, 31.725	
	Median	30.100		30.975		29.185	
	Q25, Q75	21.420, 36.470		24.060, 41.405		23.660, 34.340	
	Min, Max	14.14, 69.66		12.61, 55.31		13.32, 65.22	
	Mean (SD)	31.267 (12.3093)		31.667 (10.0520)		29.779 (10.1502)	
	95% CI of Mean	28.415, 34.120		28.452, 34.882		26.236, 33.321	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.62.2.1 Descriptive Statistics of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	%Change(*)	Value	%Change(*)	Value	%Change(*)
Day 6/Discharge Confinement	n	74	74	39	39	34	34
	Missing, n (%)	6 (7.5)	6 (7.5)	2 (4.9)	2 (4.9)	5 (12.8)	5 (12.8)
	BLOQ, n (%)	0		0		3 (8.8)	
	Geometric Mean (CV%)	31.540 (35.1265)		31.023 (33.1470)		64.895 (68.0920)	
	95% CI of Geometric Mean	29.143, 34.134		27.940, 34.447		52.322, 80.490	
	Median	34.380	7.569	32.010	0.941	70.710	144.539
	Q25, Q75	25.030, 39.800	-8.460, 22.111	26.000, 37.820	-10.143, 18.882	39.530, 91.670	69.846, 211.521
	Min, Max	16.54, 64.07	-31.72, 124.00	14.67, 58.71	-31.80, 91.80	15.97, 211.21	0.00, 486.11
	Mean (SD)	33.361 (11.1367)	11.513 (29.3835)	32.520 (9.6001)	7.193 (26.0613)	77.380 (47.2938)	156.991 (125.0169)
	95% CI of Mean	30.780, 35.942	4.705, 18.321	29.408, 35.632	-1.255, 15.642	60.878, 93.882	113.370, 200.612

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.62.2.1 Descriptive Statistics of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - FAS**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	%Change(*)	Value	%Change(*)	Value	%Change(*)
Day 90	n	73	73	39	39	33	33
	Missing, n (%)	7 (8.8)	7 (8.8)	2 (4.9)	2 (4.9)	6 (15.4)	6 (15.4)
	BLOQ, n (%)	0		0		3 (9.1)	
	Geometric Mean (CV%)	31.244 (39.8490)		33.173 (32.7814)		39.497 (43.0057)	
	95% CI of Geometric Mean	28.566, 34.172		29.909, 36.793		34.129, 45.710	
	Median	31.310	6.921	35.880	11.467	38.020	33.678
	Q25, Q75	23.470, 41.000	-9.798, 27.640	26.940, 40.650	-6.334, 33.663	30.330, 45.880	2.679, 52.269
	Min, Max	13.02, 77.26	-31.13, 123.56	13.74, 64.17	-34.74, 98.11	18.17, 91.67	-11.88, 588.21
	Mean (SD)	33.550 (12.8244)	9.715 (26.3688)	34.764 (10.4230)	14.662 (27.4967)	43.125 (20.1549)	55.911 (106.7394)
	95% CI of Mean	30.557, 36.543	3.562, 15.868	31.384, 38.143	5.748, 23.575	35.978, 50.272	18.062, 93.759

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.4.63.1 Analysis of CYP2A6 Activity (%) - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CYP2A6 Activity (%)						
Day 6/Discharge Confinement	n	74	33	23		
	Geometric LS Mean (CV%)	32.802	31.039	77.131	105.68 (25.58)	42.53 (25.58)
	95% CI	30.927, 34.791	28.442, 33.873	69.471, 85.635	95.19, 117.33	37.74, 47.92
	p-value (one-sided)				0.149	
Day 90	n	47	31	9		
	Geometric LS Mean (CV%)	30.471	32.709	48.577	93.16 (29.61)	62.73 (29.61)
	95% CI	27.966, 33.200	29.463, 36.313	39.905, 59.133	81.39, 106.63	50.70, 77.61

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant.

**Table 15.2.4.63.1.1 Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - PP Set**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CYP2A6 Activity (%)						
Day 6/Discharge Confinement	n	70	33	23		
	Geometric LS Mean (CV%)	32.278	30.766	76.287	104.91 (25.60)	42.31 (25.60)
	95% CI	30.374, 34.301	28.189, 33.578	68.707, 84.705	94.39, 116.60	37.52, 47.71
	p-value (one-sided)				0.185	
Day 90	n	45	31	8		
	Geometric LS Mean (CV%)	29.943	32.682	50.104	91.62 (28.34)	59.76 (28.34)
	95% CI	27.517, 32.583	29.564, 36.129	40.924, 61.343	80.41, 104.39	48.16, 74.15

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant.

**Table 15.2.4.63.2 Analysis of CYP2A6 Activity (%) - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CYP2A6 Activity (%)						
Day 6/Discharge Confinement	n	78	39	33		
	Geometric LS Mean (CV%)	32.604	31.042	81.605	105.03 (28.75)	39.95 (28.75)
	95% CI	30.588, 34.752	28.381, 33.951	74.019, 89.969	94.16, 117.16	35.58, 44.86
	p-value (one-sided)				0.188	
Day 90	n	73	35	31		
	Geometric LS Mean (CV%)	32.058	33.321	41.611	96.21 (27.76)	77.04 (27.76)
	95% CI	30.082, 34.164	30.404, 36.517	37.759, 45.856	86.11, 107.49	68.63, 86.49

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant.

**Table 15.2.4.63.2.1 Analysis of CYP2A6 Activity (%) Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting CYP2A6 Activity - FAS**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 : mCC Ratio (%)	THSm2.2 : SA Ratio (%)
CYP2A6 Activity (%)						
Day 6/Discharge Confinement	n	74	38	30		
	Geometric LS Mean (CV%)	31.870	30.807	75.243	103.45 (27.00)	42.36 (27.00)
	95% CI	29.954, 33.908	28.278, 33.563	68.308, 82.883	93.16, 114.88	37.80, 47.46
	p-value (one-sided)				0.261	
Day 90	n	68	35	27		
	Geometric LS Mean (CV%)	31.184	32.945	41.318	94.65 (27.01)	75.47 (27.01)
	95% CI	29.231, 33.267	30.129, 36.025	37.313, 45.752	84.84, 105.60	66.97, 85.06

Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs) from an ANCOVA model conducted on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors. Geometrical CV% of the ratio is estimated from the residual mean squares.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC. P-value at Day 90 is evaluated only if p-value at Day 5 is significant.



Table 15.2.4.64.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) - PP Set
Parameter (units): Ames Mutagenicity (REV/mL)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	63		29		21	
	Missing, n (%)	12(16.0)		6(17.1)		3(12.5)	
	Geometric Mean (CV%)	8.32 (84.882)		NC		9.58 (69.993)	
	95% CI of Geometric Mean	6.90, 10.02		NC		7.18, 12.78	
	Median	8.21		9.66		11.20	
	Q25, Q75	4.67, 15.70		5.41, 13.20		7.43, 14.00	
	Min, Max	2.1, 45.4		0.0, 28.2		2.9, 25.7	
	Mean (SD)	10.81 (8.344)		10.31 (6.907)		11.34 (6.265)	
	95% CI of Mean	8.71, 12.92		7.68, 12.94		8.49, 14.20	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N).



Table 15.2.4.64.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) - PP Set
Parameter (units): Ames Mutagenicity (REV/mL)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	63	34	29	23	21
	Missing, n (%)	2(2.7)	12(16.0)	1(2.9)	6(17.1)	1(4.2)	3(12.5)
	Geometric Mean (CV%)	NC		NC		NC	
	95% CI of Geometric Mean	NC		NC		NC	
	Median	2.08	-76.10	10.25	3.51	1.89	-77.23
	Q25, Q75	1.25, 3.45	-90.95, -50.59	4.89, 16.50	-21.97, 49.07	1.37, 5.25	-86.23, -41.07
	Min, Max	0.0, 27.7	-100.0, 47.7	0.0, 50.2	-76.8, 1618.4	0.0, 19.8	-100.0, 0.0
	Mean (SD)	3.15 (4.135)	-66.20 (34.982)	11.77 (9.592)	76.11 (304.428)	4.52 (5.609)	-62.62 (33.801)
	95% CI of Mean	2.18, 4.12	-75.01, -57.38	8.42, 15.13	-39.69, 191.91	2.09, 6.95	-78.01, -47.23

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N).



Table 15.2.4.64.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) - PP Set
Parameter (units): Ames Mutagenicity (REV/mL)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	41		28		8	
	Missing, n (%)	6(12.8)		4(12.5)		1(11.1)	
	Geometric Mean (CV%)	7.90 (86.609)		NC		8.50 (70.321)	
	95% CI of Geometric Mean	6.23, 10.01		NC		5.00, 14.44	
	Median	7.13		9.63		11.45	
	Q25, Q75	4.67, 13.00		5.16, 12.90		5.70, 12.90	
	Min, Max	2.1, 45.4		0.0, 28.2		2.9, 15.5	
	Mean (SD)	10.46 (8.904)		9.79 (6.224)		9.81 (4.630)	
	95% CI of Mean	7.64, 13.27		7.37, 12.21		5.93, 13.69	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N).



Table 15.2.4.64.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) - PP Set
Parameter (units): Ames Mutagenicity (REV/mL)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	41	32	28	9	8
	Missing, n (%)		6(12.8)		4(12.5)		1(11.1)
	Geometric Mean (CV%)	NC		9.56 (59.474)		NC	
	95% CI of Geometric Mean	NC		7.84, 11.67		NC	
	Median	3.50	-66.87	10.30	11.83	2.44	-71.64
	Q25, Q75	2.18, 6.17	-76.10, -8.72	7.28, 12.70	-26.23, 87.56	1.37, 5.32	-91.81, -49.55
	Min, Max	0.0, 25.9	-100.0, 222.2	2.2, 26.2	-74.5, 1230.0	0.0, 6.6	-100.0, -41.1
	Mean (SD)	4.50 (4.129)	-36.35 (72.830)	10.90 (5.484)	88.72 (255.207)	2.89 (2.557)	-70.88 (23.484)
	95% CI of Mean	3.28, 5.71	-59.34, -13.35	8.92, 12.89	-10.24, 187.68	0.92, 4.86	-90.52, -51.25

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N).



Table 15.2.4.64.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) - PP Set
Parameter (units): Ames Mutagenicity (REV/24h)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	63		29		21	
	Missing, n (%)	12(16.0)		6(17.1)		3(12.5)	
	Geometric Mean (CV%)	20417.66 (113.410)		NC		22805.19 (80.144)	
	95% CI of Geometric Mean	16238.56, 25672.29		NC		16549.83, 31424.89	
	Median	19463.24		17384.40		25823.00	
	Q25, Q75	11335.09, 41937.90		13321.90, 29915.74		14999.40, 35294.00	
	Min, Max	2416.2, 148367.2		0.0, 81244.2		5611.2, 80368.2	
	Mean (SD)	30251.24 (29094.282)		24798.69 (19446.807)		28259.41 (18515.293)	
	95% CI of Mean	22923.94, 37578.55		17401.52, 32195.87		19831.34, 36687.47	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N).



Table 15.2.4.64.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) - PP Set
Parameter (units): Ames Mutagenicity (REV/24h)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	73	63	34	29	23	21
	Missing, n (%)	2(2.7)	12(16.0)	1(2.9)	6(17.1)	1(4.2)	3(12.5)
	Geometric Mean (CV%)	NC		NC		NC	
	95% CI of Geometric Mean	NC		NC		NC	
	Median	5800.74	-73.28	30608.70	51.73	3920.18	-76.00
	Q25, Q75	2559.90, 10487.70	-90.48, -46.97	10705.24, 60928.00	0.00, 138.11	2426.58, 11398.00	-89.12, -56.75
	Min, Max	0.0, 43350.4	-100.0, 39.9	0.0, 129114.4	-75.9, 1587.1	0.0, 80368.2	-100.0, 0.0
	Mean (SD)	8438.27 (9523.211)	-61.95 (37.150)	36544.33 (29684.109)	111.05 (298.746)	10806.29 (17858.405)	-66.85 (31.807)
	95% CI of Mean	6216.33, 10660.20	-71.31, -52.58	26187.05, 46901.61	-2.59, 224.69	3083.73, 18528.84	-81.33, -52.37

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N).



Table 15.2.4.64.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) - PP Set
Parameter (units): Ames Mutagenicity (REV/24h)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	41		28		8	
	Missing, n (%)	6(12.8)		4(12.5)		1(11.1)	
	Geometric Mean (CV%)	18869.55 (116.605)		NC		19414.99 (69.654)	
	95% CI of Geometric Mean	14084.72, 25279.87		NC		11476.06, 32845.91	
	Median	18668.75		17131.64		24980.40	
	Q25, Q75	12698.84, 38707.20		12990.39, 28621.90		11834.10, 31967.00	
	Min, Max	2416.2, 148367.2		0.0, 81244.2		6900.5, 35294.0	
	Mean (SD)	28352.92 (29045.675)		23283.64 (17577.460)		22469.69 (10997.892)	
	95% CI of Mean	19184.97, 37520.87		16467.81, 30099.47		13275.21, 31664.16	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N).



Table 15.2.4.64.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) - PP Set
Parameter (units): Ames Mutagenicity (REV/24h)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	47	41	32	28	9	8
	Missing, n (%)		6(12.8)		4(12.5)		1(11.1)
	Geometric Mean (CV%)	NC		22527.26 (76.434)		NC	
	95% CI of Geometric Mean	NC		17640.10, 28768.38		NC	
	Median	7439.08	-61.58	22047.46	10.88	6178.08	-67.89
	Q25, Q75	5692.40, 14407.25	-81.19, 0.00	14426.10, 29134.00	-34.57, 106.34	3440.07, 10453.80	-90.46, -54.37
	Min, Max	0.0, 53250.4	-100.0, 256.2	5968.1, 87139.8	-81.7, 2357910.0	0.0, 13607.2	-100.0, -50.1
	Mean (SD)	10308.49 (8808.979)	-34.67 (74.264)	28405.28 (21825.957)	84287.29 (445588.213)	6322.92 (4817.130)	-71.95 (20.014)
	95% CI of Mean	7722.07, 12894.91	-58.11, -11.22	20536.18, 36274.39	-88493.79, 257068.37	2620.14, 10025.70	-88.69, -55.21

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.4.64.2 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) - FAS****Parameter (units): Ames Mutagenicity (REV/mL)**

		THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
Timepoint	Statistic	Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		35		34	
	Missing, n (%)	13(16.3)		6(14.6)		5(12.8)	
	Geometric Mean (CV%)	8.33 (83.117)		NC		10.60 (62.897)	
	95% CI of Geometric Mean	6.97, 9.94		NC		8.66, 12.97	
	Median	8.21		9.77		11.75	
	Q25, Q75	4.67, 15.70		5.41, 16.10		7.80, 15.80	
	Min, Max	2.1, 45.4		0.0, 33.4		2.9, 27.4	
	Mean (SD)	10.74 (8.170)		11.52 (8.231)		12.22 (6.096)	
	95% CI of Mean	8.74, 12.74		8.68, 14.35		10.08, 14.35	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.4.64.2 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) - FAS****Parameter (units): Ames Mutagenicity (REV/mL)**

		THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
Timepoint	Statistic	Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	77	67	40	35	37	34
	Missing, n (%)	3(3.8)	13(16.3)	1(2.4)	6(14.6)	2(5.1)	5(12.8)
	Geometric Mean (CV%)	NC		NC		NC	
	95% CI of Geometric Mean	NC		NC		NC	
	Median	2.08	-75.25	10.35	2.48	2.54	-71.18
	Q25, Q75	1.26, 3.45	-90.70, -48.17	5.28, 17.10	-24.39, 49.07	1.46, 6.32	-86.23, -40.12
	Min, Max	0.0, 27.7	-100.0, 47.7	0.0, 50.2	-76.8, 1618.4	0.0, 27.4	-100.0, 0.0
	Mean (SD)	3.15 (4.038)	-65.79 (34.414)	12.25 (9.473)	63.78 (278.242)	5.28 (6.567)	-59.64 (36.285)
	95% CI of Mean	2.22, 4.07	-74.18, -57.39	9.21, 15.28	-31.81, 159.36	3.08, 7.47	-72.31, -46.97

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.4.64.2 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) - FAS****Parameter (units): Ames Mutagenicity (REV/mL)**

		THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
Timepoint	Statistic	Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	77	67	40	35	37	34
	Missing, n (%)	3(3.8)	13(16.3)	1(2.4)	6(14.6)	2(5.1)	5(12.8)
	Geometric Mean (CV%)	NC		10.57 (64.527)		NC	
	95% CI of Geometric Mean	NC		8.75, 12.77		NC	
	Median	3.50	-65.82	10.75	10.68	3.53	-61.56
	Q25, Q75	2.18, 5.79	-76.35, -12.19	7.43, 17.95	-28.57, 81.73	1.61, 6.72	-86.35, -15.39
	Min, Max	0.0, 25.9	-100.0, 222.2	2.2, 26.8	-74.5, 1618.4	0.0, 27.4	-100.0, 2.8
	Mean (SD)	4.42 (3.744)	-41.69 (62.226)	12.32 (6.574)	118.06 (348.078)	5.74 (6.385)	-54.37 (37.286)
	95% CI of Mean	3.56, 5.27	-56.87, -26.51	10.21, 14.42	-1.51, 237.64	3.60, 7.87	-67.38, -41.35

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.4.64.2 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) - FAS****Parameter (units): Ames Mutagenicity (REV/24h)**

		THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
Timepoint	Statistic	Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	67		35		34	
	Missing, n (%)	13(16.3)		6(14.6)		5(12.8)	
	Geometric Mean (CV%)	20262.78 (112.422)		NC		25382.66 (71.283)	
	95% CI of Geometric Mean	16253.39, 25261.19		NC		20295.82, 31744.44	
	Median	19237.20		20849.50		26406.80	
	Q25, Q75	11335.09, 41937.90		13321.90, 38088.24		19281.40, 37150.80	
	Min, Max	2416.2, 148367.2		0.0, 86330.6		5611.2, 80368.2	
	Mean (SD)	29938.09 (28694.564)		28335.18 (22318.148)		30280.40 (17279.315)	
	95% CI of Mean	22938.93, 36937.25		20668.62, 36001.73		24251.35, 36309.44	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.4.64.2 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) - FAS****Parameter (units): Ames Mutagenicity (REV/24h)**

		THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
Timepoint	Statistic	Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 5	n	77	67	40	35	37	34
	Missing, n (%)	3(3.8)	13(16.3)	1(2.4)	6(14.6)	2(5.1)	5(12.8)
	Geometric Mean (CV%)	NC		NC		NC	
	95% CI of Geometric Mean	NC		NC		NC	
	Median	5823.94	-72.04	32894.60	40.44	6455.75	-74.00
	Q25, Q75	2695.98, 10487.70	-90.11, -46.97	17845.02, 59763.20	-12.32, 138.11	2708.37, 16336.55	-89.12, -50.14
	Min, Max	0.0, 43350.4	-100.0, 61.1	0.0, 129114.4	-75.9, 1587.1	0.0, 80368.2	-100.0, 0.0
	Mean (SD)	8438.56 (9287.763)	-60.44 (39.112)	37632.01 (28344.187)	99.14 (275.557)	12740.18 (17194.833)	-61.71 (35.758)
	95% CI of Mean	6330.49, 10546.63	-69.99, -50.90	28567.10, 46696.93	4.48, 193.80	7007.13, 18473.23	-74.19, -49.23

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.4.64.2 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) - FAS****Parameter (units): Ames Mutagenicity (REV/24h)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	77	67	40	35	37	34
	Missing, n (%)	3(3.8)	13(16.3)	1(2.4)	6(14.6)	2(5.1)	5(12.8)
	Geometric Mean (CV%)	NC		25594.78 (76.509)		NC	
	95% CI of Geometric Mean	NC		20599.96, 31800.67		NC	
	Median	7457.78	-65.94	24346.71	1.95	6708.90	-67.36
	Q25, Q75	5692.40, 13958.20	-81.19, -22.93	17312.70, 42297.00	-29.69, 112.50	3373.05, 17025.80	-91.76, -37.04
	Min, Max	0.0, 53250.4	-100.0, 256.2	5968.1, 87139.8	-81.7, 2357910.0	0.0, 80368.2	-100.0, 0.0
	Mean (SD)	10037.67 (8512.335)	-40.30 (69.137)	31837.54 (21907.413)	67476.07 (398541.004)	13045.82 (16980.693)	-58.56 (35.391)
	95% CI of Mean	8105.60, 11969.74	-57.17, -23.43	24831.20, 38843.87	-69427.56, 204379.70	7384.17, 18707.47	-70.91, -46.20

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.4.65 Descriptive Statistics of Visual Inspection of the THS 2.2 Menthol Tobacco Plugs Data - FAS**

Timepoint	Evaluation	THSm2.2 (N=80) [n of THSm2.2 products used =976]	
		n	%
Day 1	0	940	(99.6%)
	1	4	(0.4%)
	Missing	32	

Note: THSm2.2 = Tobacco Heating System.

Note: Percentages are based on the number of non-missing inspections.

Note: 0 = No overheating, 1 = White spot(s) inside the tobacco plug, 2 = Ashes inside the tobacco plug and burnt paper.

Note: Missing values assessed as the difference between the number of sticks used and the number of sticks for which visual inspection of the plug has been performed.

**Table 15.2.4.65 Descriptive Statistics of Visual Inspection of the THS 2.2 Menthol Tobacco Plugs Data - FAS**

Timepoint	Evaluation	THSm2.2 (N=80) [n of THSm2.2 products used =1079]	
		n	%
Day 2	0	1030	(99.8%)
	1	2	(0.2%)
	Missing	47	

Note: THSm2.2 = Tobacco Heating System.

Note: Percentages are based on the number of non-missing inspections.

Note: 0 = No overheating, 1 = White spot(s) inside the tobacco plug, 2 = Ashes inside the tobacco plug and burnt paper.

Note: Missing values assessed as the difference between the number of sticks used and the number of sticks for which visual inspection of the plug has been performed.

**Table 15.2.4.65 Descriptive Statistics of Visual Inspection of the THS 2.2 Menthol Tobacco Plugs Data - FAS**

Timepoint	Evaluation	THSm2.2 (N=80) [n of THSm2.2 products used =1171]	
		n	%
Day 3	0	1142	(99.1%)
	1	10	(0.9%)
	Missing	19	

Note: THSm2.2 = Tobacco Heating System.

Note: Percentages are based on the number of non-missing inspections.

Note: 0 = No overheating, 1 = White spot(s) inside the tobacco plug, 2 = Ashes inside the tobacco plug and burnt paper.

Note: Missing values assessed as the difference between the number of sticks used and the number of sticks for which visual inspection of the plug has been performed.

**Table 15.2.4.65 Descriptive Statistics of Visual Inspection of the THS 2.2 Menthol Tobacco Plugs Data - FAS**

Timepoint	Evaluation	THSm2.2 (N=80) [n of THSm2.2 products used =1144]	
		n	%
Day 4	0	1100	(99.2%)
	1	8	(0.7%)
	2	1	(0.1%)
	Missing	35	

Note: THSm2.2 = Tobacco Heating System.

Note: Percentages are based on the number of non-missing inspections.

Note: 0 = No overheating, 1 = White spot(s) inside the tobacco plug, 2 = Ashes inside the tobacco plug and burnt paper.

Note: Missing values assessed as the difference between the number of sticks used and the number of sticks for which visual inspection of the plug has been performed.

**Table 15.2.4.65 Descriptive Statistics of Visual Inspection of the THS 2.2 Menthol Tobacco Plugs Data - FAS**

Timepoint	Evaluation	THSm2.2 (N=80) [n of THSm2.2 products used =1259]	
		n	%
Day 5	0	1217	(98.7%)
	1	15	(1.2%)
	2	1	(0.1%)
	Missing	26	

Note: THSm2.2 = Tobacco Heating System.

Note: Percentages are based on the number of non-missing inspections.

Note: 0 = No overheating, 1 = White spot(s) inside the tobacco plug, 2 = Ashes inside the tobacco plug and burnt paper.

Note: Missing values assessed as the difference between the number of sticks used and the number of sticks for which visual inspection of the plug has been performed.

**Table 15.2.4.65 Descriptive Statistics of Visual Inspection of the THS 2.2 Menthol Tobacco Plugs Data - FAS**

Timepoint	Evaluation	THSm2.2 (N=80) [n of THSm2.2 products used =6]	
		n	%
Day 6/Discharge Confinement	0	6	(100.0%)

Note: THSm2.2 = Tobacco Heating System.

Note: Percentages are based on the number of non-missing inspections.

Note: 0 = No overheating, 1 = White spot(s) inside the tobacco plug, 2 = Ashes inside the tobacco plug and burnt paper.

Note: Missing values assessed as the difference between the number of sticks used and the number of sticks for which visual inspection of the plug has been performed.

**Table 15.2.4.65 Descriptive Statistics of Visual Inspection of the THS 2.2 Menthol Tobacco Plugs Data - FAS**

Timepoint	Evaluation	THSm2.2 (N=80) [n of THSm2.2 products used =885]	
		n	%
Day 30	0	874	(99.1%)
	1	8	(0.9%)
	Missing	3	

Note: THSm2.2 = Tobacco Heating System.

Note: Percentages are based on the number of non-missing inspections.

Note: 0 = No overheating, 1 = White spot(s) inside the tobacco plug, 2 = Ashes inside the tobacco plug and burnt paper.

Note: Missing values assessed as the difference between the number of sticks used and the number of sticks for which visual inspection of the plug has been performed.

**Table 15.2.4.65 Descriptive Statistics of Visual Inspection of the THS 2.2 Menthol Tobacco Plugs Data - FAS**

Timepoint	Evaluation	THSm2.2 (N=80)	
		[n of THSm2.2 products used =794] n	%
Day 60	0	771	(99.9%)
	1	1	(0.1%)
	Missing	22	

Note: THSm2.2 = Tobacco Heating System.

Note: Percentages are based on the number of non-missing inspections.

Note: 0 = No overheating, 1 = White spot(s) inside the tobacco plug, 2 = Ashes inside the tobacco plug and burnt paper.

Note: Missing values assessed as the difference between the number of sticks used and the number of sticks for which visual inspection of the plug has been performed.

**Table 15.2.4.65 Descriptive Statistics of Visual Inspection of the THS 2.2 Menthol Tobacco Plugs Data - FAS**

Timepoint	Evaluation	THSm2.2 (N=80)	
		[n of THSm2.2 products used =760] n	%
Day 90	0	709	(99.6%)
	1	3	(0.4%)
	Missing	48	

Note: THSm2.2 = Tobacco Heating System.

Note: Percentages are based on the number of non-missing inspections.

Note: 0 = No overheating, 1 = White spot(s) inside the tobacco plug, 2 = Ashes inside the tobacco plug and burnt paper.

Note: Missing values assessed as the difference between the number of sticks used and the number of sticks for which visual inspection of the plug has been performed.

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 6a-hydroxy-5a-cholestane (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	66		30		21	
	Missing, n (%)	9 (12.0)		5 (14.3)		3 (12.5)	
	BLOQ, n (%)	5 (7.6)		3 (10.0)		0	
	Geometric Mean (CV%)	27.75 (66.953)		29.11 (82.251)		31.82 (50.043)	
	95% CI of Geometric Mean	23.89, 32.24		22.25, 38.07		25.65, 39.46	
	Median	27.95		28.81		33.15	
	Q25, Q75	20.65, 43.08		19.82, 45.51		24.12, 43.21	
	Min, Max	6.9, 107.9		6.9, 137.8		14.2, 77.3	
	Mean (SD)	32.92 (19.983)		37.02 (28.341)		35.28 (16.322)	
	95% CI of Mean	28.00, 37.84		26.43, 47.61		27.84, 42.71	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 6a-hydroxy-5a-cholestane (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	66	66	30	30	21	21
	Missing, n (%)	9 (12.0)	9 (12.0)	5 (14.3)	5 (14.3)	3 (12.5)	3 (12.5)
	BLOQ, n (%)	12 (18.2)		6 (20.0)		3 (14.3)	
	Geometric Mean (CV%)	20.78 (73.219)		22.80 (92.813)		25.25 (87.832)	
	95% CI of Geometric Mean	17.68, 24.41		16.98, 30.61		17.89, 35.63	
	Median	21.01	-24.44	24.34	-19.08	26.41	-20.27
	Q25, Q75	15.44, 33.19	-38.00, 0.00	14.62, 39.29	-37.57, 2.88	16.99, 40.78	-37.03, 13.24
	Min, Max	6.9, 71.7	-74.2, 105.1	6.9, 122.3	-67.4, 113.4	6.9, 122.4	-65.7, 58.4
	Mean (SD)	25.20 (15.266)	-20.15 (29.125)	30.32 (24.486)	-14.08 (38.074)	32.86 (26.450)	-13.61 (35.099)
	95% CI of Mean	21.44, 28.95	-27.31, -12.98	21.18, 39.47	-28.31, 0.14	20.82, 44.91	-29.59, 2.37

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 6a-hydroxy-5a-cholestane (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Appendix 15.3.6.22

Study ID: ZRHM-REXA-08-US

Program: t_oxyst_pp.sas

Status: Final

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**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 6a-hydroxy-5a-cholestane (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	46		31		9	
	Missing, n (%)	1 (2.1)		1 (3.1)		0	
	BLOQ, n (%)	3 (6.5)		3 (9.7)		0	
	Geometric Mean (CV%)	30.72 (69.326)		28.88 (80.681)		21.57 (38.678)	
	95% CI of Geometric Mean	25.50, 37.00		22.27, 37.45		16.18, 28.74	
	Median	31.64		28.78		19.84	
	Q25, Q75	20.82, 46.08		19.82, 45.51		15.89, 26.98	
	Min, Max	6.9, 107.9		6.9, 137.8		14.2, 43.2	
	Mean (SD)	36.66 (22.112)		36.56 (27.979)		23.02 (9.393)	
	95% CI of Mean	30.08, 43.23		26.30, 46.83		15.80, 30.24	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 6a-hydroxy-5a-cholestane (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	46	46	31	31	9	9
	Missing, n (%)	1 (2.1)	1 (2.1)	1 (3.1)	1 (3.1)	0	0
	BLOQ, n (%)	3 (6.5)		1 (3.2)		1 (11.1)	
	Geometric Mean (CV%)	31.33 (61.511)		31.07 (72.657)		20.61 (53.709)	
	95% CI of Geometric Mean	26.47, 37.07		24.46, 39.45		13.99, 30.35	
	Median	33.95	2.97	25.44	3.69	22.09	-2.96
	Q25, Q75	23.11, 45.58	-22.99, 20.56	19.61, 49.69	-11.43, 29.11	17.39, 29.27	-7.91, 8.49
	Min, Max	6.9, 81.2	-54.1, 380.6	6.9, 174.7	-44.4, 158.2	6.9, 39.8	-51.7, 48.4
	Mean (SD)	35.73 (16.753)	11.95 (65.092)	38.98 (32.716)	14.05 (44.221)	22.69 (9.472)	-0.93 (26.271)
	95% CI of Mean	30.75, 40.71	-7.39, 31.28	26.98, 50.99	-2.17, 30.28	15.41, 29.98	-21.13, 19.27

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 7a-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	66		30		21	
	Missing, n (%)	9 (12.0)		5 (14.3)		3 (12.5)	
	BLOQ, n (%)	10 (15.2)		5 (16.7)		5 (23.8)	
	Geometric Mean (CV%)	25.78 (94.324)		23.26 (81.946)		21.39 (88.475)	
	95% CI of Geometric Mean	21.18, 31.37		17.79, 30.40		15.12, 30.24	
	Median	26.37		24.46		27.88	
	Q25, Q75	17.42, 42.48		17.56, 39.37		15.14, 35.82	
	Min, Max	6.7, 245.2		6.7, 119.5		6.7, 67.3	
	Mean (SD)	35.68 (36.294)		29.37 (21.982)		27.11 (17.321)	
	95% CI of Mean	26.75, 44.61		21.16, 37.58		19.23, 35.00	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 7a-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	66	66	30	30	21	21
	Missing, n (%)	9 (12.0)	9 (12.0)	5 (14.3)	5 (14.3)	3 (12.5)	3 (12.5)
	BLOQ, n (%)	4 (6.1)		4 (13.3)		2 (9.5)	
	Geometric Mean (CV%)	32.53 (76.569)		26.45 (82.197)		31.88 (75.829)	
	95% CI of Geometric Mean	27.52, 38.45		20.22, 34.59		23.45, 43.33	
	Median	33.17	25.63	27.81	12.69	42.59	29.43
	Q25, Q75	20.65, 48.33	-2.24, 85.30	19.08, 39.50	-3.86, 64.64	23.40, 50.73	13.59, 101.11
	Min, Max	6.7, 132.0	-90.0, 422.0	6.7, 112.2	-65.1, 229.0	6.7, 69.5	-57.5, 755.7
	Mean (SD)	40.46 (28.305)	49.50 (90.480)	33.18 (23.036)	30.29 (68.815)	37.72 (18.282)	92.44 (179.910)
	95% CI of Mean	33.49, 47.42	27.26, 71.75	24.57, 41.78	4.59, 55.99	29.40, 46.05	10.55, 174.34

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 7a-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Appendix 15.3.6.22

Study ID: ZRHM-REXA-08-US

Program: t_oxyst_pp.sas

Status: Final

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**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 7a-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	46		31		9	
	Missing, n (%)	1 (2.1)		1 (3.1)		0	
	BLOQ, n (%)	7 (15.2)		5 (16.1)		3 (33.3)	
	Geometric Mean (CV%)	25.99 (89.662)		23.57 (80.765)		17.19 (98.766)	
	95% CI of Geometric Mean	20.68, 32.65		18.17, 30.58		9.11, 32.42	
	Median	27.88		26.45		16.42	
	Q25, Q75	18.66, 40.17		17.56, 39.37		6.73, 35.82	
	Min, Max	6.7, 133.2		6.7, 119.5		6.7, 61.0	
	Mean (SD)	34.21 (27.513)		29.56 (21.638)		23.01 (18.397)	
	95% CI of Mean	26.03, 42.38		21.62, 37.50		8.86, 37.16	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 7a-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	46	46	31	31	9	9
	Missing, n (%)	1 (2.1)	1 (2.1)	1 (3.1)	1 (3.1)	0	0
	BLOQ, n (%)	4 (8.7)		2 (6.5)		3 (33.3)	
	Geometric Mean (CV%)	35.95 (104.516)		31.01 (73.912)		16.47 (105.759)	
	95% CI of Geometric Mean	27.85, 46.40		24.33, 39.51		8.46, 32.07	
	Median	31.58	47.99	32.00	28.86	14.86	-31.04
	Q25, Q75	20.14, 66.66	0.00, 116.62	19.70, 49.90	-3.68, 82.26	6.73, 24.70	-31.43, 54.52
	Min, Max	6.7, 214.7	-81.0, 339.8	6.7, 174.3	-51.9, 336.0	6.7, 94.2	-59.0, 264.2
	Mean (SD)	50.27 (43.169)	63.47 (88.685)	38.27 (29.970)	45.80 (75.539)	24.17 (27.422)	23.60 (104.557)
	95% CI of Mean	37.45, 63.10	37.13, 89.81	27.27, 49.27	18.09, 73.52	3.08, 45.25	-56.78, 103.97

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 5a,6a-epoxycholestanol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	66		30		21	
	Missing, n (%)	9 (12.0)		5 (14.3)		3 (12.5)	
	BLOQ, n (%)	15 (22.7)		6 (20.0)		1 (4.8)	
	Geometric Mean (CV%)	18.62 (76.917)		17.61 (68.129)		20.95 (48.216)	
	95% CI of Geometric Mean	15.74, 22.02		13.98, 22.19		17.01, 25.80	
	Median	20.62		19.83		20.56	
	Q25, Q75	14.15, 32.05		14.18, 28.46		17.03, 26.24	
	Min, Max	6.2, 54.0		6.2, 51.5		6.2, 44.4	
	Mean (SD)	22.66 (12.676)		20.71 (11.020)		22.99 (9.937)	
	95% CI of Mean	19.53, 25.78		16.59, 24.83		18.46, 27.52	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 5a,6a-epoxycholestanol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	66	66	30	30	21	21
	Missing, n (%)	9 (12.0)	9 (12.0)	5 (14.3)	5 (14.3)	3 (12.5)	3 (12.5)
	BLOQ, n (%)	16 (24.2)		8 (26.7)		1 (4.8)	
	Geometric Mean (CV%)	17.45 (78.916)		15.41 (68.112)		21.34 (66.629)	
	95% CI of Geometric Mean	14.70, 20.71		12.23, 19.41		16.19, 28.13	
	Median	19.07	-0.85	17.77	-0.17	17.17	-5.04
	Q25, Q75	12.69, 29.13	-17.53, 5.47	6.23, 24.53	-14.72, 2.32	14.96, 28.03	-18.06, 10.36
	Min, Max	6.2, 71.8	-66.9, 191.2	6.2, 44.1	-67.1, 75.0	6.2, 102.2	-49.0, 396.9
	Mean (SD)	21.73 (14.161)	0.45 (41.443)	18.17 (9.833)	-8.19 (27.129)	26.00 (20.585)	16.14 (90.588)
	95% CI of Mean	18.24, 25.21	-9.74, 10.64	14.50, 21.85	-18.33, 1.94	16.62, 35.37	-25.10, 57.38

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 5a,6a-epoxycholestanol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	46		31		9	
	Missing, n (%)	1 (2.1)		1 (3.1)		0	
	BLOQ, n (%)	13 (28.3)		6 (19.4)		2 (22.2)	
	Geometric Mean (CV%)	16.39 (76.432)		17.90 (67.601)		18.77 (74.705)	
	95% CI of Geometric Mean	13.40, 20.06		14.29, 22.42		11.25, 31.33	
	Median	18.88		20.74		25.25	
	Q25, Q75	6.23, 31.03		14.18, 28.49		17.61, 26.24	
	Min, Max	6.2, 47.1		6.2, 51.5		6.2, 40.5	
	Mean (SD)	19.97 (11.360)		20.97 (10.932)		22.02 (10.964)	
	95% CI of Mean	16.59, 23.35		16.95, 24.98		13.59, 30.45	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 5a,6a-epoxycholestanol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	46	46	31	31	9	9
	Missing, n (%)	1 (2.1)	1 (2.1)	1 (3.1)	1 (3.1)	0	0
	BLOQ, n (%)	13 (28.3)		5 (16.1)		1 (11.1)	
	Geometric Mean (CV%)	15.91 (74.987)		17.45 (61.110)		23.68 (71.010)	
	95% CI of Geometric Mean	13.05, 19.41		14.19, 21.46		14.49, 38.70	
	Median	17.32	0.00	18.40	-5.06	23.41	13.10
	Q25, Q75	6.23, 28.86	-17.07, 8.24	13.67, 25.35	-15.97, 14.16	21.40, 38.10	-5.97, 31.26
	Min, Max	6.2, 43.8	-68.1, 184.6	6.2, 43.0	-67.1, 143.2	6.2, 54.7	-12.4, 165.9
	Mean (SD)	19.33 (11.058)	7.00 (50.960)	20.01 (9.862)	4.17 (42.421)	27.59 (14.518)	36.87 (65.099)
	95% CI of Mean	16.04, 22.62	-8.14, 22.14	16.38, 23.63	-11.39, 19.74	16.43, 38.76	-13.17, 86.92

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 7-ketocholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	66		30		21	
	Missing, n (%)	9 (12.0)		5 (14.3)		3 (12.5)	
	BLOQ, n (%)	6 (9.1)		4 (13.3)		0	
	Geometric Mean (CV%)	29.86 (60.917)		26.65 (68.929)		32.90 (35.500)	
	95% CI of Geometric Mean	26.01, 34.29		21.11, 33.64		28.12, 38.49	
	Median	32.88		31.39		32.57	
	Q25, Q75	24.01, 43.32		18.01, 42.03		24.69, 44.49	
	Min, Max	7.7, 87.2		7.7, 68.9		20.0, 59.5	
	Mean (SD)	34.05 (16.037)		31.22 (15.773)		34.82 (12.060)	
	95% CI of Mean	30.11, 38.00		25.32, 37.11		29.32, 40.31	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 7-ketocholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	66	66	30	30	21	21
	Missing, n (%)	9 (12.0)	9 (12.0)	5 (14.3)	5 (14.3)	3 (12.5)	3 (12.5)
	BLOQ, n (%)	1 (1.5)		5 (16.7)		1 (4.8)	
	Geometric Mean (CV%)	29.04 (44.762)		24.07 (68.435)		32.51 (60.509)	
	95% CI of Geometric Mean	26.14, 32.26		19.09, 30.34		25.21, 41.92	
	Median	30.26	-4.34	26.95	-5.87	30.87	5.23
	Q25, Q75	20.30, 38.55	-16.99, 11.36	18.30, 37.88	-26.08, 7.83	22.61, 48.40	-23.34, 28.14
	Min, Max	7.7, 74.6	-63.8, 150.9	7.7, 64.8	-57.1, 119.1	7.7, 71.9	-74.9, 141.8
	Mean (SD)	31.69 (13.415)	2.92 (39.673)	28.21 (14.432)	-3.50 (38.910)	37.18 (18.684)	10.51 (51.871)
	95% CI of Mean	28.38, 34.99	-6.83, 12.68	22.81, 33.60	-18.04, 11.03	28.67, 45.69	-13.11, 34.13

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 7-ketocholesterol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	46		31		9	
	Missing, n (%)	1 (2.1)		1 (3.1)		0	
	BLOQ, n (%)	5 (10.9)		4 (12.9)		1 (11.1)	
	Geometric Mean (CV%)	28.33 (64.341)		26.86 (67.749)		28.59 (61.413)	
	95% CI of Geometric Mean	23.79, 33.75		21.44, 33.66		18.50, 44.17	
	Median	31.98		31.45		34.37	
	Q25, Q75	20.51, 39.87		18.01, 42.03		25.26, 39.74	
	Min, Max	7.7, 87.2		7.7, 68.9		7.7, 50.4	
	Mean (SD)	32.74 (16.338)		31.31 (15.516)		31.94 (12.974)	
	95% CI of Mean	27.88, 37.59		25.62, 37.01		21.96, 41.92	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 7-ketocholesterol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	46	46	31	31	9	9
	Missing, n (%)	1 (2.1)	1 (2.1)	1 (3.1)	1 (3.1)	0	0
	BLOQ, n (%)	3 (6.5)		3 (9.7)		1 (11.1)	
	Geometric Mean (CV%)	29.63 (56.043)		28.02 (60.544)		30.67 (65.989)	
	95% CI of Geometric Mean	25.37, 34.61		22.83, 34.41		19.32, 48.70	
	Median	31.54	2.59	30.41	-3.06	37.33	8.98
	Q25, Q75	23.58, 41.78	-17.45, 44.39	20.61, 43.90	-17.56, 10.22	24.02, 44.35	-11.68, 21.60
	Min, Max	7.7, 86.4	-76.8, 247.1	7.7, 59.9	-57.1, 234.8	7.7, 52.5	-30.1, 53.5
	Mean (SD)	33.39 (15.905)	17.77 (60.439)	31.84 (14.486)	17.25 (67.257)	34.72 (14.763)	10.30 (27.236)
	95% CI of Mean	28.66, 38.12	-0.18, 35.72	26.52, 37.16	-7.42, 41.93	23.37, 46.08	-10.64, 31.24

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 7b-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	66		30		21	
	Missing, n (%)	9 (12.0)		5 (14.3)		3 (12.5)	
	BLOQ, n (%)	66 (100.0)		30 (100.0)		21 (100.0)	
	Geometric Mean (CV%)	6.43 (0.000)		6.43 (0.000)		6.43 (0.000)	
	95% CI of Geometric Mean	NC, NC		NC, NC		NC, NC	
	Median	6.43		6.43		6.43	
	Q25, Q75	6.43, 6.43		6.43, 6.43		6.43, 6.43	
	Min, Max	6.4, 6.4		6.4, 6.4		6.4, 6.4	
	Mean (SD)	6.43 (0.000)		6.43 (0.000)		6.43 (0.000)	
	95% CI of Mean	NC, NC		NC, NC		NC, NC	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 7b-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	66	66	30	30	21	21
	Missing, n (%)	9 (12.0)	9 (12.0)	5 (14.3)	5 (14.3)	3 (12.5)	3 (12.5)
	BLOQ, n (%)	66 (100.0)		30 (100.0)		20 (95.2)	
	Geometric Mean (CV%)	6.43 (0.000)		6.43 (0.000)		6.85 (29.806)	
	95% CI of Geometric Mean	NC, NC		NC, NC		6.00, 7.83	
	Median	6.43	0.00	6.43	0.00	6.43	0.00
	Q25, Q75	6.43, 6.43	0.00, 0.00	6.43, 6.43	0.00, 0.00	6.43, 6.43	0.00, 0.00
	Min, Max	6.4, 6.4	0.0, 0.0	6.4, 6.4	0.0, 0.0	6.4, 24.5	0.0, 280.7
	Mean (SD)	6.43 (0.000)	0.00 (0.000)	6.43 (0.000)	0.00 (0.000)	7.29 (3.939)	13.37 (61.258)
	95% CI of Mean	NC, NC	NC, NC	NC, NC	NC, NC	5.49, 9.09	-14.52, 41.26

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 7b-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	46		31		9	
	Missing, n (%)	1 (2.1)		1 (3.1)		0	
	BLOQ, n (%)	46 (100.0)		31 (100.0)		9 (100.0)	
	Geometric Mean (CV%)	6.43 (0.000)		6.43 (0.000)		6.43 (0.000)	
	95% CI of Geometric Mean	NC, NC		NC, NC		NC, NC	
	Median	6.43		6.43		6.43	
	Q25, Q75	6.43, 6.43		6.43, 6.43		6.43, 6.43	
	Min, Max	6.4, 6.4		6.4, 6.4		6.4, 6.4	
	Mean (SD)	6.43 (0.000)		6.43 (0.000)		6.43 (0.000)	
	95% CI of Mean	NC, NC		NC, NC		NC, NC	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 7b-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	46	46	31	31	9	9
	Missing, n (%)	1 (2.1)	1 (2.1)	1 (3.1)	1 (3.1)	0	0
	BLOQ, n (%)	45 (97.8)		31 (100.0)		9 (100.0)	
	Geometric Mean (CV%)	6.55 (12.854)		6.43 (0.000)		6.43 (0.000)	
	95% CI of Geometric Mean	6.30, 6.81		NC, NC		NC, NC	
	Median	6.43	0.00	6.43	0.00	6.43	0.00
	Q25, Q75	6.43, 6.43	0.00, 0.00	6.43, 6.43	0.00, 0.00	6.43, 6.43	0.00, 0.00
	Min, Max	6.4, 15.3	0.0, 138.3	6.4, 6.4	0.0, 0.0	6.4, 6.4	0.0, 0.0
	Mean (SD)	6.62 (1.311)	3.01 (20.386)	6.43 (0.000)	0.00 (0.000)	6.43 (0.000)	0.00 (0.000)
	95% CI of Mean	6.23, 7.02	-3.05, 9.06	NC, NC	NC, NC	NC, NC	NC, NC

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 5b,6b-epoxycholestanol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	66		30		21	
	Missing, n (%)	9 (12.0)		5 (14.3)		3 (12.5)	
	BLOQ, n (%)	9 (13.6)		5 (16.7)		3 (14.3)	
	Geometric Mean (CV%)	54.17 (84.058)		45.39 (79.858)		51.69 (82.380)	
	95% CI of Geometric Mean	45.26, 64.85		34.91, 59.01		37.24, 71.73	
	Median	56.97		48.10		59.25	
	Q25, Q75	36.71, 100.53		29.13, 78.89		33.56, 78.00	
	Min, Max	13.4, 201.9		13.4, 173.3		13.4, 146.9	
	Mean (SD)	67.88 (41.868)		56.11 (35.553)		63.71 (38.119)	
	95% CI of Mean	57.58, 78.17		42.83, 69.39		46.35, 81.07	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 5b,6b-epoxycholestanol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge	n	66	66	30	30	21	21
Confinement	Missing, n (%)	9 (12.0)	9 (12.0)	5 (14.3)	5 (14.3)	3 (12.5)	3 (12.5)
	BLOQ, n (%)	11 (16.7)		6 (20.0)		4 (19.0)	
	Geometric Mean (CV%)	49.55 (86.926)		41.82 (78.606)		52.65 (114.580)	
	95% CI of Geometric Mean	41.20, 59.59		32.28, 54.19		34.70, 79.89	
	Median	54.94	-4.41	43.33	0.00	52.93	0.00
	Q25, Q75	34.02, 84.11	-20.22, 6.93	33.01, 67.29	-9.14, 13.32	33.13, 99.09	-17.78, 29.37
	Min, Max	13.4, 307.1	-64.2, 142.3	13.4, 170.8	-72.7, 66.6	13.4, 390.7	-58.3, 179.6
	Mean (SD)	64.26 (50.833)	-3.58 (33.460)	51.72 (34.224)	-3.20 (27.329)	78.84 (84.942)	11.42 (51.237)
	95% CI of Mean	51.76, 76.76	-11.81, 4.65	38.94, 64.50	-13.41, 7.01	40.17, 117.51	-11.91, 34.74

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 5b,6b-epoxycholestanol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	46		31		9	
	Missing, n (%)	1 (2.1)		1 (3.1)		0	
	BLOQ, n (%)	8 (17.4)		5 (16.1)		1 (11.1)	
	Geometric Mean (CV%)	47.06 (81.189)		46.29 (79.383)		60.44 (77.729)	
	95% CI of Geometric Mean	38.09, 58.14		35.81, 59.82		35.63, 102.52	
	Median	51.69		48.78		73.83	
	Q25, Q75	33.90, 85.77		29.13, 82.48		56.80, 78.00	
	Min, Max	13.4, 133.0		13.4, 173.3		13.4, 139.7	
	Mean (SD)	58.21 (34.616)		56.98 (35.291)		71.21 (36.364)	
	95% CI of Mean	47.93, 68.50		44.03, 69.93		43.25, 99.17	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 5b,6b-epoxycholestanol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	46	46	31	31	9	9
	Missing, n (%)	1 (2.1)	1 (2.1)	1 (3.1)	1 (3.1)	0	0
	BLOQ, n (%)	9 (19.6)		5 (16.1)		1 (11.1)	
	Geometric Mean (CV%)	45.79 (86.733)		46.45 (73.920)		69.56 (92.309)	
	95% CI of Geometric Mean	36.65, 57.19		36.45, 59.18		38.04, 127.19	
	Median	48.92	0.00	51.15	0.00	68.36	15.54
	Q25, Q75	31.98, 88.62	-14.40, 13.54	36.53, 77.38	-11.44, 20.65	61.63, 110.44	-5.38, 41.59
	Min, Max	13.4, 124.3	-73.3, 159.9	13.4, 144.1	-39.6, 66.1	13.4, 227.4	-58.9, 203.2
	Mean (SD)	58.00 (35.969)	5.77 (46.130)	55.64 (31.210)	2.95 (23.858)	87.75 (61.247)	30.32 (73.174)
	95% CI of Mean	47.32, 68.69	-7.94, 19.47	44.19, 67.10	-5.81, 11.70	40.67, 134.84	-25.93, 86.57

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set**

Parameter (units): 24(R)-hydroxycholesterol (ng/mL)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	66		30		21	
	Missing, n (%)	9 (12.0)		5 (14.3)		3 (12.5)	
	Geometric Mean (CV%)	47.54 (27.446)		49.73 (34.346)		50.37 (25.326)	
	95% CI of Geometric Mean	44.49, 50.80		43.89, 56.34		44.96, 56.42	
	Median	47.54		50.74		49.81	
	Q25, Q75	39.98, 54.65		39.46, 62.98		45.04, 53.26	
	Min, Max	22.7, 103.9		22.7, 108.0		26.0, 82.2	
	Mean (SD)	49.31 (14.134)		52.45 (17.746)		51.86 (12.977)	
	95% CI of Mean	45.83, 52.79		45.82, 59.08		45.95, 57.77	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 24(R)-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	66	66	30	30	21	21
	Missing, n (%)	9 (12.0)	9 (12.0)	5 (14.3)	5 (14.3)	3 (12.5)	3 (12.5)
	Geometric Mean (CV%)	46.20 (26.886)		46.50 (32.716)		47.93 (39.105)	
	95% CI of Geometric Mean	43.29, 49.31		41.27, 52.38		40.37, 56.92	
	Median	44.70	-1.82	48.79	-7.15	49.25	-5.96
	Q25, Q75	38.70, 53.89	-10.77, 4.02	39.31, 54.95	-12.21, 0.70	42.96, 62.93	-12.13, 8.62
	Min, Max	21.8, 108.5	-26.9, 44.9	23.8, 101.0	-25.5, 18.4	12.5, 72.1	-52.2, 36.0
	Mean (SD)	47.87 (13.640)	-2.11 (12.091)	48.85 (16.225)	-5.86 (11.197)	50.59 (14.370)	-2.70 (19.878)
	95% CI of Mean	44.51, 51.23	-5.08, 0.87	42.79, 54.91	-10.05, -1.68	44.04, 57.13	-11.75, 6.35

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set**

Parameter (units): 24(R)-hydroxycholesterol (ng/mL)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	46		31		9	
	Missing, n (%)	1 (2.1)		1 (3.1)		0	
	Geometric Mean (CV%)	49.14 (26.348)		49.84 (33.762)		42.25 (26.200)	
	95% CI of Geometric Mean	45.50, 53.08		44.17, 56.23		34.65, 51.51	
	Median	47.77		50.97		44.99	
	Q25, Q75	42.36, 54.84		39.46, 62.98		39.45, 47.18	
	Min, Max	26.8, 103.9		22.7, 108.0		26.0, 61.5	
	Mean (SD)	50.87 (14.564)		52.48 (17.449)		43.46 (10.554)	
	95% CI of Mean	46.54, 55.20		46.07, 58.88		35.34, 51.57	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 24(R)-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	46	46	31	31	9	9
	Missing, n (%)	1 (2.1)	1 (2.1)	1 (3.1)	1 (3.1)	0	0
	Geometric Mean (CV%)	49.70 (27.399)		49.40 (31.081)		41.56 (25.894)	
	95% CI of Geometric Mean	45.87, 53.83		44.19, 55.23		34.17, 50.56	
	Median	48.01	2.57	47.41	-0.69	45.27	0.62
	Q25, Q75	40.37, 59.48	-7.20, 9.66	40.60, 60.37	-8.49, 5.14	32.82, 48.88	-13.47, 7.07
	Min, Max	33.9, 103.7	-33.7, 69.0	26.5, 98.8	-25.0, 29.1	27.9, 57.5	-16.8, 19.3
	Mean (SD)	51.62 (15.615)	2.48 (17.324)	51.70 (16.450)	-0.24 (11.588)	42.74 (10.355)	-0.94 (12.286)
	95% CI of Mean	46.98, 56.26	-2.67, 7.63	45.66, 57.74	-4.49, 4.02	34.77, 50.70	-10.39, 8.50

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 25-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	66		30		21	
	Missing, n (%)	9 (12.0)		5 (14.3)		3 (12.5)	
	BLOQ, n (%)	10 (15.2)		4 (13.3)		1 (4.8)	
	Geometric Mean (CV%)	5.78 (45.562)		5.70 (41.471)		6.41 (30.590)	
	95% CI of Geometric Mean	5.19, 6.44		4.90, 6.61		5.59, 7.35	
	Median	6.33		6.20		6.79	
	Q25, Q75	5.17, 7.50		5.44, 6.78		5.49, 7.76	
	Min, Max	2.4, 12.6		2.4, 10.9		2.4, 9.5	
	Mean (SD)	6.27 (2.283)		6.09 (2.012)		6.64 (1.630)	
	95% CI of Mean	5.70, 6.83		5.33, 6.84		5.90, 7.39	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 25-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	66	66	30	30	21	21
	Missing, n (%)	9 (12.0)	9 (12.0)	5 (14.3)	5 (14.3)	3 (12.5)	3 (12.5)
	BLOQ, n (%)	12 (18.2)		4 (13.3)		3 (14.3)	
	Geometric Mean (CV%)	5.20 (43.219)		5.35 (37.850)		5.72 (42.873)	
	95% CI of Geometric Mean	4.69, 5.77		4.66, 6.14		4.74, 6.90	
	Median	5.72	-7.25	5.69	-6.15	6.60	-1.31
	Q25, Q75	4.85, 6.88	-17.85, 0.00	5.00, 6.72	-15.94, 1.47	5.26, 7.37	-14.30, 2.54
	Min, Max	2.4, 9.2	-61.0, 162.6	2.4, 8.6	-55.6, 103.4	2.4, 9.6	-66.1, 25.9
	Mean (SD)	5.60 (1.894)	-5.74 (33.596)	5.66 (1.675)	-3.58 (24.528)	6.12 (1.970)	-7.27 (21.847)
	95% CI of Mean	5.13, 6.07	-14.00, 2.53	5.03, 6.29	-12.74, 5.59	5.22, 7.02	-17.22, 2.68

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 25-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	46		31		9	
	Missing, n (%)	1 (2.1)		1 (3.1)		0	
	BLOQ, n (%)	7 (15.2)		4 (12.9)		1 (11.1)	
	Geometric Mean (CV%)	5.75 (45.126)		5.71 (40.732)		5.56 (39.881)	
	95% CI of Geometric Mean	5.05, 6.54		4.94, 6.59		4.13, 7.48	
	Median	6.37		6.12		5.68	
	Q25, Q75	5.17, 7.50		5.44, 6.78		5.20, 6.41	
	Min, Max	2.4, 12.6		2.4, 10.9		2.4, 8.6	
	Mean (SD)	6.22 (2.216)		6.08 (1.978)		5.89 (1.917)	
	95% CI of Mean	5.55, 6.88		5.35, 6.81		4.41, 7.37	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 25-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	46	46	31	31	9	9
	Missing, n (%)	1 (2.1)	1 (2.1)	1 (3.1)	1 (3.1)	0	0
	BLOQ, n (%)	6 (13.0)		4 (12.9)		1 (11.1)	
	Geometric Mean (CV%)	5.68 (41.734)		5.72 (41.133)		5.51 (36.273)	
	95% CI of Geometric Mean	5.04, 6.40		4.94, 6.61		4.20, 7.22	
	Median	5.90	-1.37	6.00	1.10	6.19	-0.19
	Q25, Q75	5.13, 7.11	-14.97, 10.59	5.29, 7.31	-7.04, 13.79	5.19, 7.05	-13.84, 16.14
	Min, Max	2.4, 11.0	-65.7, 185.1	2.4, 11.0	-60.9, 123.4	2.4, 7.4	-62.2, 105.1
	Mean (SD)	6.08 (2.043)	9.82 (55.323)	6.10 (2.004)	5.42 (35.950)	5.77 (1.560)	7.62 (45.159)
	95% CI of Mean	5.47, 6.69	-6.61, 26.25	5.36, 6.84	-7.77, 18.61	4.56, 6.97	-27.10, 42.34

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 22(R)-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	66		30		21	
	Missing, n (%)	9 (12.0)		5 (14.3)		3 (12.5)	
	BLOQ, n (%)	66 (100.0)		30 (100.0)		21 (100.0)	
	Geometric Mean (CV%)	4.73 (0.000)		4.73 (0.000)		4.73 (0.000)	
	95% CI of Geometric Mean	NC, NC		NC, NC		NC, NC	
	Median	4.73		4.73		4.73	
	Q25, Q75	4.73, 4.73		4.73, 4.73		4.73, 4.73	
	Min, Max	4.7, 4.7		4.7, 4.7		4.7, 4.7	
	Mean (SD)	4.73 (0.000)		4.73 (0.000)		4.73 (0.000)	
	95% CI of Mean	NC, NC		NC, NC		NC, NC	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 22(R)-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	66	66	30	30	21	21
	Missing, n (%)	9 (12.0)	9 (12.0)	5 (14.3)	5 (14.3)	3 (12.5)	3 (12.5)
	BLOQ, n (%)	66 (100.0)		30 (100.0)		21 (100.0)	
	Geometric Mean (CV%)	4.73 (0.000)		4.73 (0.000)		4.73 (0.000)	
	95% CI of Geometric Mean	NC, NC		NC, NC		NC, NC	
	Median	4.73	0.00	4.73	0.00	4.73	0.00
	Q25, Q75	4.73, 4.73	0.00, 0.00	4.73, 4.73	0.00, 0.00	4.73, 4.73	0.00, 0.00
	Min, Max	4.7, 4.7	0.0, 0.0	4.7, 4.7	0.0, 0.0	4.7, 4.7	0.0, 0.0
	Mean (SD)	4.73 (0.000)	0.00 (0.000)	4.73 (0.000)	0.00 (0.000)	4.73 (0.000)	0.00 (0.000)
	95% CI of Mean	NC, NC	NC, NC	NC, NC	NC, NC	NC, NC	NC, NC

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 22(R)-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	46		31		9	
	Missing, n (%)	1 (2.1)		1 (3.1)		0	
	BLOQ, n (%)	46 (100.0)		31 (100.0)		9 (100.0)	
	Geometric Mean (CV%)	4.73 (0.000)		4.73 (0.000)		4.73 (0.000)	
	95% CI of Geometric Mean	NC, NC		NC, NC		NC, NC	
	Median	4.73		4.73		4.73	
	Q25, Q75	4.73, 4.73		4.73, 4.73		4.73, 4.73	
	Min, Max	4.7, 4.7		4.7, 4.7		4.7, 4.7	
	Mean (SD)	4.73 (0.000)		4.73 (0.000)		4.73 (0.000)	
	95% CI of Mean	NC, NC		NC, NC		NC, NC	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 22(R)-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	46	46	31	31	9	9
	Missing, n (%)	1 (2.1)	1 (2.1)	1 (3.1)	1 (3.1)	0	0
	BLOQ, n (%)	46 (100.0)		31 (100.0)		9 (100.0)	
	Geometric Mean (CV%)	4.73 (0.000)		4.73 (0.000)		4.73 (0.000)	
	95% CI of Geometric Mean	NC, NC		NC, NC		NC, NC	
	Median	4.73	0.00	4.73	0.00	4.73	0.00
	Q25, Q75	4.73, 4.73	0.00, 0.00	4.73, 4.73	0.00, 0.00	4.73, 4.73	0.00, 0.00
	Min, Max	4.7, 4.7	0.0, 0.0	4.7, 4.7	0.0, 0.0	4.7, 4.7	0.0, 0.0
	Mean (SD)	4.73 (0.000)	0.00 (0.000)	4.73 (0.000)	0.00 (0.000)	4.73 (0.000)	0.00 (0.000)
	95% CI of Mean	NC, NC	NC, NC	NC, NC	NC, NC	NC, NC	NC, NC

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 4b-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	66		30		21	
	Missing, n (%)	9 (12.0)		5 (14.3)		3 (12.5)	
	BLOQ, n (%)	2 (3.0)		1 (3.3)		1 (4.8)	
	Geometric Mean (CV%)	21.13 (43.414)		19.84 (48.514)		24.07 (57.407)	
	95% CI of Geometric Mean	19.07, 23.41		16.71, 23.56		18.87, 30.69	
	Median	21.14		20.73		24.13	
	Q25, Q75	16.94, 26.53		12.82, 27.30		19.15, 34.11	
	Min, Max	5.3, 57.2		5.3, 46.4		5.3, 76.7	
	Mean (SD)	22.90 (9.565)		21.79 (9.182)		27.33 (14.740)	
	95% CI of Mean	20.55, 25.26		18.36, 25.22		20.61, 34.04	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 4b-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	66	66	30	30	21	21
	Missing, n (%)	9 (12.0)	9 (12.0)	5 (14.3)	5 (14.3)	3 (12.5)	3 (12.5)
	BLOQ, n (%)	3 (4.5)		2 (6.7)		1 (4.8)	
	Geometric Mean (CV%)	18.49 (43.572)		16.94 (48.324)		20.53 (50.660)	
	95% CI of Geometric Mean	16.68, 20.49		14.27, 20.10		16.51, 25.52	
	Median	19.01	-11.28	17.59	-13.22	20.07	-10.31
	Q25, Q75	14.92, 23.32	-23.40, 1.26	12.57, 25.24	-26.76, -2.49	16.73, 25.26	-20.27, 5.36
	Min, Max	5.3, 48.9	-64.7, 27.8	5.3, 31.3	-57.1, 125.7	5.3, 68.5	-59.0, 26.3
	Mean (SD)	20.03 (8.193)	-10.51 (18.336)	18.53 (7.317)	-10.02 (33.044)	22.88 (12.332)	-11.38 (22.962)
	95% CI of Mean	18.01, 22.05	-15.03, -6.00	15.79, 21.27	-22.36, 2.33	17.26, 28.50	-21.84, -0.92

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 4b-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Appendix 15.3.6.22

Study ID: ZRHM-REXA-08-US

Program: t_oxyst_pp.sas

Status: Final

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**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 4b-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	46		31		9	
	Missing, n (%)	1 (2.1)		1 (3.1)		0	
	BLOQ, n (%)	2 (4.3)		1 (3.2)		1 (11.1)	
	Geometric Mean (CV%)	19.32 (43.171)		19.62 (48.133)		21.56 (67.829)	
	95% CI of Geometric Mean	17.08, 21.85		16.59, 23.20		13.43, 34.61	
	Median	19.49		20.59		22.43	
	Q25, Q75	16.16, 24.08		12.82, 27.30		19.86, 31.25	
	Min, Max	5.3, 57.2		5.3, 46.4		5.3, 40.7	
	Mean (SD)	20.88 (8.503)		21.53 (9.138)		24.62 (11.210)	
	95% CI of Mean	18.35, 23.41		18.18, 24.89		16.00, 33.24	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 4b-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	46	46	31	31	9	9
	Missing, n (%)	1 (2.1)	1 (2.1)	1 (3.1)	1 (3.1)	0	0
	BLOQ, n (%)	3 (6.5)		4 (12.9)		1 (11.1)	
	Geometric Mean (CV%)	17.64 (49.460)		16.81 (64.549)		21.31 (72.816)	
	95% CI of Geometric Mean	15.35, 20.28		13.53, 20.87		12.90, 35.18	
	Median	16.88	-8.46	16.76	-7.02	20.41	-4.83
	Q25, Q75	14.05, 25.38	-20.60, 5.56	12.31, 25.36	-18.55, 2.88	18.78, 27.44	-12.19, 22.72
	Min, Max	5.3, 51.1	-64.7, 51.4	5.3, 50.3	-61.7, 37.4	5.3, 65.6	-40.3, 72.4
	Mean (SD)	19.51 (8.961)	-5.78 (22.794)	19.58 (10.629)	-10.98 (22.746)	25.35 (16.544)	3.36 (33.694)
	95% CI of Mean	16.84, 22.17	-12.56, 0.99	15.67, 23.48	-19.33, -2.63	12.63, 38.07	-22.54, 29.27

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 27-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	66		30		21	
	Missing, n (%)	9 (12.0)		5 (14.3)		3 (12.5)	
	Geometric Mean (CV%)	134.43 (30.819)		142.66 (34.225)		154.34 (28.347)	
	95% CI of Geometric Mean	124.83, 144.77		125.99, 161.55		135.99, 175.17	
	Median	129.47		139.72		157.62	
	Q25, Q75	111.96, 159.78		122.70, 173.13		126.74, 197.19	
	Min, Max	65.3, 311.3		62.0, 332.8		82.6, 247.2	
	Mean (SD)	140.82 (46.385)		150.71 (54.240)		159.91 (42.340)	
	95% CI of Mean	129.42, 152.23		130.45, 170.96		140.63, 179.19	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 27-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	66	66	30	30	21	21
	Missing, n (%)	9 (12.0)	9 (12.0)	5 (14.3)	5 (14.3)	3 (12.5)	3 (12.5)
	Geometric Mean (CV%)	125.50 (26.932)		130.04 (37.793)		142.94 (39.540)	
	95% CI of Geometric Mean	117.59, 133.94		113.45, 149.05		120.17, 170.02	
	Median	123.85	-5.53	135.26	-10.03	164.81	-3.46
	Q25, Q75	105.94, 155.62	-12.33, 0.36	103.89, 162.97	-17.52, 0.27	122.49, 182.02	-9.52, 0.02
	Min, Max	69.6, 256.8	-33.5, 21.2	45.3, 267.9	-31.9, 21.1	38.3, 230.2	-53.7, 28.2
	Mean (SD)	130.00 (36.104)	-6.08 (10.242)	138.10 (47.225)	-7.98 (13.017)	151.09 (43.542)	-5.32 (18.789)
	95% CI of Mean	121.12, 138.88	-8.60, -3.56	120.46, 155.74	-12.84, -3.11	131.27, 170.92	-13.88, 3.24

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 27-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	46		31		9	
	Missing, n (%)	1 (2.1)		1 (3.1)		0	
	Geometric Mean (CV%)	134.70 (29.770)		141.41 (34.014)		138.80 (31.594)	
	95% CI of Geometric Mean	123.53, 146.88		125.25, 159.66		109.49, 175.94	
	Median	129.47		139.61		144.87	
	Q25, Q75	111.96, 153.31		117.94, 173.13		112.05, 184.71	
	Min, Max	65.3, 311.1		62.0, 332.8		82.6, 200.4	
	Mean (SD)	140.57 (44.019)		149.35 (53.862)		144.60 (42.683)	
	95% CI of Mean	127.49, 153.65		129.59, 169.11		111.79, 177.41	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): 27-hydroxycholesterol (ng/mL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	46	46	31	31	9	9
	Missing, n (%)	1 (2.1)	1 (2.1)	1 (3.1)	1 (3.1)	0	0
	Geometric Mean (CV%)	134.85 (29.523)		144.86 (36.469)		142.47 (26.940)	
	95% CI of Geometric Mean	123.76, 146.95		127.24, 164.91		116.24, 174.62	
	Median	129.95	1.48	140.97	2.21	151.81	-2.54
	Q25, Q75	108.52, 164.78	-9.02, 8.15	119.68, 187.20	-7.20, 10.74	128.18, 174.98	-9.77, 11.87
	Min, Max	75.0, 308.9	-34.9, 55.3	57.5, 340.2	-21.0, 34.9	92.4, 195.3	-13.7, 35.5
	Mean (SD)	140.65 (43.488)	1.22 (15.223)	153.84 (56.243)	3.29 (13.625)	146.71 (35.565)	3.75 (16.526)
	95% CI of Mean	127.73, 153.57	-3.31, 5.74	133.20, 174.47	-1.71, 8.29	119.37, 174.05	-8.96, 16.46

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): Cholesterol (mg/dL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	66		30		21	
	Missing, n (%)	9 (12.0)		5 (14.3)		3 (12.5)	
	Geometric Mean (CV%)	137.91 (23.734)		139.61 (27.951)		148.01 (19.272)	
	95% CI of Geometric Mean	130.19, 146.08		126.02, 154.68		135.68, 161.45	
	Median	140.00		135.50		154.00	
	Q25, Q75	114.00, 162.00		118.00, 169.00		135.00, 168.00	
	Min, Max	80.0, 231.0		78.0, 282.0		102.0, 223.0	
	Mean (SD)	141.65 (33.108)		144.93 (42.292)		150.57 (28.481)	
	95% CI of Mean	133.51, 149.80		129.14, 160.73		137.60, 163.54	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): Cholesterol (mg/dL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	66	66	30	30	21	21
	Missing, n (%)	9 (12.0)	9 (12.0)	5 (14.3)	5 (14.3)	3 (12.5)	3 (12.5)
	BLOQ, n (%)	0		0		1 (4.8)	
	Geometric Mean (CV%)	129.80 (21.836)		123.76 (27.463)		133.57 (47.176)	
	95% CI of Geometric Mean	123.09, 136.87		111.90, 136.87		108.91, 163.81	
	Median	132.00	-6.10	126.00	-11.73	140.00	-1.67
	Q25, Q75	112.00, 147.00	-15.48, 2.65	99.00, 153.00	-18.82, -4.55	122.00, 166.00	-20.47, 13.13
	Min, Max	80.0, 200.0	-35.5, 65.0	69.0, 201.0	-30.6, 15.7	25.0, 241.0	-75.5, 33.3
	Mean (SD)	132.77 (28.411)	-4.75 (15.612)	128.07 (33.588)	-10.56 (12.241)	143.29 (44.374)	-5.02 (26.114)
	95% CI of Mean	125.78, 139.76	-8.59, -0.90	115.52, 140.61	-15.14, -5.99	123.08, 163.49	-16.91, 6.88

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): Cholesterol (mg/dL)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

Appendix 15.3.6.22

Study ID: ZRHM-REXA-08-US

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Status: Final

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**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): Cholesterol (mg/dL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	46		31		9	
	Missing, n (%)	1 (2.1)		1 (3.1)		0	
	Geometric Mean (CV%)	135.68 (25.610)		138.86 (27.642)		136.11 (19.391)	
	95% CI of Geometric Mean	125.89, 146.23		125.70, 153.40		117.42, 157.78	
	Median	137.00		135.00		139.00	
	Q25, Q75	113.00, 162.00		118.00, 169.00		116.00, 160.00	
	Min, Max	80.0, 231.0		78.0, 282.0		102.0, 171.0	
	Mean (SD)	139.96 (35.560)		144.06 (41.861)		138.33 (26.005)	
	95% CI of Mean	129.39, 150.52		128.70, 159.42		118.34, 158.33	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set****Parameter (units): Cholesterol (mg/dL)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	46	46	31	31	9	9
	Missing, n (%)	1 (2.1)	1 (2.1)	1 (3.1)	1 (3.1)	0	0
	Geometric Mean (CV%)	135.97 (26.240)		137.04 (24.475)		126.12 (32.050)	
	95% CI of Geometric Mean	125.94, 146.81		125.43, 149.72		99.17, 160.39	
	Median	135.00	-0.69	131.00	-1.54	133.00	-6.86
	Q25, Q75	109.00, 164.00	-8.48, 16.31	120.00, 166.00	-8.45, 7.69	95.00, 168.00	-15.45, 5.00
	Min, Max	84.0, 255.0	-31.4, 36.3	88.0, 239.0	-20.2, 23.0	87.0, 188.0	-25.0, 9.9
	Mean (SD)	140.59 (38.047)	1.46 (15.928)	141.03 (35.446)	-0.61 (12.084)	131.67 (40.522)	-6.56 (12.672)
	95% CI of Mean	129.28, 151.89	-3.28, 6.19	128.03, 154.04	-5.05, 3.83	100.51, 162.82	-16.31, 3.18

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 6a-hydroxy-5a-cholestane (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		35		30	
	Missing, n (%)	10 (12.5)		6 (14.6)		9 (23.1)	
	BLOQ, n (%)	6 (8.6)		4 (11.4)		0	
	Geometric Mean (CV%)	27.46 (68.016)		28.44 (84.872)		29.45 (48.719)	
	95% CI of Geometric Mean	23.70, 31.82		22.07, 36.63		24.78, 34.99	
	Median	28.12		28.78		28.09	
	Q25, Q75	20.65, 42.99		18.39, 48.16		19.50, 43.10	
	Min, Max	6.9, 107.9		6.9, 137.8		14.2, 77.3	
	Mean (SD)	32.64 (19.677)		36.48 (27.692)		32.66 (15.500)	
	95% CI of Mean	27.94, 37.33		26.96, 46.00		26.87, 38.46	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 6a-hydroxy-5a-cholestane (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge	n	70	70	35	35	30	30
Confinement	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	13 (18.6)		7 (20.0)		4 (13.3)	
	Geometric Mean (CV%)	20.82 (73.466)		22.58 (92.028)		23.48 (80.571)	
	95% CI of Geometric Mean	17.80, 24.36		17.25, 29.55		18.03, 30.58	
	Median	21.42	-22.67	22.48	-18.95	22.78	-19.26
	Q25, Q75	15.44, 33.19	-37.29, 0.00	14.62, 39.29	-34.04, 0.00	15.63, 40.78	-35.32, 9.97
	Min, Max	6.9, 71.7	-74.2, 105.1	6.9, 122.3	-67.4, 113.4	6.9, 122.4	-65.7, 58.4
	Mean (SD)	25.24 (15.119)	-19.27 (28.768)	29.94 (23.789)	-14.03 (35.282)	29.86 (23.402)	-14.43 (31.457)
	95% CI of Mean	21.63, 28.85	-26.14, -12.41	21.76, 38.12	-26.15, -1.91	21.11, 38.60	-26.19, -2.68

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 6a-hydroxy-5a-cholestane (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	35	35	30	30
	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	5 (7.1)		2 (5.7)		1 (3.3)	
	Geometric Mean (CV%)	28.83 (60.732)		30.34 (79.148)		28.98 (60.645)	
	95% CI of Geometric Mean	25.22, 32.96		23.87, 38.56		23.51, 35.72	
	Median	31.45	5.16	25.44	2.32	27.97	-3.73
	Q25, Q75	21.41, 42.80	-17.42, 21.94	18.05, 51.09	-11.43, 29.11	21.05, 40.76	-17.35, 12.80
	Min, Max	6.9, 81.2	-54.1, 380.6	6.9, 174.7	-44.4, 158.2	6.9, 112.3	-51.7, 173.3
	Mean (SD)	32.90 (15.619)	13.64 (58.576)	38.76 (32.040)	12.63 (42.148)	33.75 (20.898)	3.58 (39.161)
	95% CI of Mean	29.17, 36.63	-0.33, 27.61	27.75, 49.77	-1.85, 27.12	25.95, 41.56	-11.05, 18.20

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 7a-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		35		30	
	Missing, n (%)	10 (12.5)		6 (14.6)		9 (23.1)	
	BLOQ, n (%)	10 (14.3)		6 (17.1)		6 (20.0)	
	Geometric Mean (CV%)	26.23 (93.933)		24.60 (88.628)		22.48 (87.171)	
	95% CI of Geometric Mean	21.70, 31.71		18.94, 31.96		16.97, 29.77	
	Median	26.37		27.49		25.70	
	Q25, Q75	17.42, 42.91		17.56, 42.82		15.14, 35.82	
	Min, Max	6.7, 245.2		6.7, 119.5		6.7, 93.0	
	Mean (SD)	36.14 (35.864)		31.98 (24.809)		28.79 (20.236)	
	95% CI of Mean	27.58, 44.70		23.45, 40.51		21.23, 36.35	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 7a-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge	n	70	70	35	35	30	30
Confinement	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	4 (5.7)		4 (11.4)		3 (10.0)	
	Geometric Mean (CV%)	33.75 (78.977)		27.75 (80.681)		30.89 (80.855)	
	95% CI of Geometric Mean	28.58, 39.85		21.75, 35.40		23.70, 40.26	
	Median	33.79	30.91	27.84	9.93	38.52	28.87
	Q25, Q75	21.10, 50.57	0.00, 86.05	19.08, 41.09	-6.19, 64.64	19.59, 52.56	0.00, 96.58
	Min, Max	6.7, 132.0	-90.0, 422.0	6.7, 112.2	-65.1, 229.0	6.7, 92.9	-59.8, 755.7
	Mean (SD)	42.55 (30.841)	51.23 (88.432)	34.74 (24.303)	29.56 (70.335)	37.70 (21.077)	76.58 (158.951)
	95% CI of Mean	35.19, 49.91	30.14, 72.32	26.38, 43.09	5.40, 53.73	29.83, 45.58	17.23, 135.94

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 7a-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	35	35	30	30
	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	8 (11.4)		3 (8.6)		5 (16.7)	
	Geometric Mean (CV%)	34.17 (110.796)		33.11 (91.710)		25.75 (114.156)	
	95% CI of Geometric Mean	27.60, 42.30		25.31, 43.31		18.30, 36.22	
	Median	29.89	24.78	33.47	30.63	24.13	5.76
	Q25, Q75	20.06, 68.76	-4.68, 104.18	19.70, 56.50	0.00, 82.26	14.36, 59.07	-31.24, 91.71
	Min, Max	6.7, 214.7	-81.0, 557.7	6.7, 174.3	-51.9, 336.0	6.7, 141.5	-70.9, 468.4
	Mean (SD)	49.30 (43.949)	57.90 (104.961)	44.50 (39.665)	49.09 (76.057)	38.50 (37.179)	47.21 (115.781)
	95% CI of Mean	38.81, 59.78	32.86, 82.93	30.87, 58.13	22.96, 75.22	24.61, 52.38	3.97, 90.45

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 5a,6a-epoxycholestanol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		35		30	
	Missing, n (%)	10 (12.5)		6 (14.6)		9 (23.1)	
	BLOQ, n (%)	16 (22.9)		8 (22.9)		2 (6.7)	
	Geometric Mean (CV%)	18.78 (77.841)		17.19 (71.088)		22.43 (61.984)	
	95% CI of Geometric Mean	15.93, 22.13		13.79, 21.42		18.12, 27.75	
	Median	21.10		18.92		21.87	
	Q25, Q75	14.15, 32.05		13.33, 28.49		17.03, 35.77	
	Min, Max	6.2, 54.0		6.2, 51.5		6.2, 96.8	
	Mean (SD)	22.93 (12.969)		20.45 (11.128)		26.27 (16.991)	
	95% CI of Mean	19.84, 26.03		16.62, 24.28		19.92, 32.62	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 5a,6a-epoxycholestanol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge	n	70	70	35	35	30	30
Confinement	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	16 (22.9)		9 (25.7)		1 (3.3)	
	Geometric Mean (CV%)	18.14 (81.985)		16.05 (69.310)		22.94 (65.922)	
	95% CI of Geometric Mean	15.28, 21.52		12.94, 19.91		18.32, 28.71	
	Median	19.47	0.00	19.64	0.00	20.92	-6.86
	Q25, Q75	12.70, 29.47	-16.95, 7.51	6.23, 25.19	-14.72, 5.47	15.40, 36.35	-18.57, 23.19
	Min, Max	6.2, 114.6	-66.9, 191.2	6.2, 44.1	-67.1, 457.8	6.2, 102.2	-49.0, 396.9
	Mean (SD)	23.16 (17.740)	4.36 (45.507)	18.97 (10.058)	5.86 (82.666)	27.72 (20.014)	14.55 (79.272)
	95% CI of Mean	18.92, 27.39	-6.50, 15.22	15.51, 22.43	-22.54, 34.26	20.24, 35.19	-15.06, 44.15

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 5a,6a-epoxycholestanol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	35	35	30	30
	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	15 (21.4)		5 (14.3)		3 (10.0)	
	Geometric Mean (CV%)	18.97 (79.606)		17.70 (57.782)		21.84 (66.118)	
	95% CI of Geometric Mean	16.05, 22.42		14.71, 21.28		17.44, 27.35	
	Median	21.82	0.00	20.30	-3.14	21.76	-5.74
	Q25, Q75	13.31, 31.83	-11.58, 15.46	13.67, 25.19	-15.97, 14.32	15.42, 36.41	-14.03, 21.52
	Min, Max	6.2, 72.7	-68.1, 184.6	6.2, 43.0	-67.1, 283.3	6.2, 81.1	-80.1, 165.9
	Mean (SD)	23.61 (15.323)	9.65 (47.276)	20.03 (9.375)	14.40 (64.495)	25.75 (15.544)	7.64 (49.712)
	95% CI of Mean	19.95, 27.27	-1.63, 20.93	16.80, 23.25	-7.76, 36.56	19.94, 31.56	-10.93, 26.20

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 7-ketocholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		35		30	
	Missing, n (%)	10 (12.5)		6 (14.6)		9 (23.1)	
	BLOQ, n (%)	6 (8.6)		4 (11.4)		1 (3.3)	
	Geometric Mean (CV%)	30.21 (60.440)		27.30 (65.993)		32.67 (47.637)	
	95% CI of Geometric Mean	26.44, 34.51		22.20, 33.57		27.59, 38.69	
	Median	33.20		31.33		33.47	
	Q25, Q75	24.01, 43.32		20.55, 42.03		24.26, 48.55	
	Min, Max	7.7, 87.2		7.7, 69.0		7.7, 78.3	
	Mean (SD)	34.42 (16.308)		31.75 (16.107)		35.75 (14.978)	
	95% CI of Mean	30.53, 38.32		26.21, 37.28		30.16, 41.35	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 7-ketocholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge	n	70	70	35	35	30	30
Confinement	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	1 (1.4)		5 (14.3)		1 (3.3)	
	Geometric Mean (CV%)	29.92 (46.174)		24.85 (65.329)		32.66 (55.785)	
	95% CI of Geometric Mean	26.94, 33.24		20.24, 30.50		26.88, 39.67	
	Median	31.18	-2.37	27.40	-2.21	30.81	-3.42
	Q25, Q75	21.07, 41.24	-15.31, 12.96	18.30, 37.88	-26.08, 9.83	23.05, 54.37	-27.13, 28.14
	Min, Max	7.7, 82.8	-63.8, 150.9	7.7, 64.8	-57.1, 119.1	7.7, 71.9	-74.9, 209.4
	Mean (SD)	32.84 (14.555)	4.80 (39.547)	28.78 (14.068)	-3.26 (37.073)	36.87 (17.769)	12.34 (59.035)
	95% CI of Mean	29.37, 36.32	-4.64, 14.23	23.94, 33.62	-16.00, 9.48	30.23, 43.51	-9.71, 34.39

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 7-ketocholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	35	35	30	30
	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	4 (5.7)		3 (8.6)		1 (3.3)	
	Geometric Mean (CV%)	31.51 (56.538)		28.53 (58.071)		32.74 (50.433)	
	95% CI of Geometric Mean	27.79, 35.73		23.70, 34.34		27.40, 39.12	
	Median	32.32	2.59	30.41	0.00	34.88	-5.29
	Q25, Q75	24.56, 47.67	-11.13, 38.70	21.72, 43.90	-17.56, 10.22	24.02, 43.31	-18.74, 23.66
	Min, Max	7.7, 87.8	-76.8, 247.1	7.7, 59.9	-57.1, 234.8	7.7, 85.2	-40.6, 65.6
	Mean (SD)	35.57 (16.840)	15.73 (55.975)	32.15 (14.204)	16.36 (63.971)	36.21 (16.243)	3.82 (28.691)
	95% CI of Mean	31.55, 39.59	2.37, 29.08	27.27, 37.04	-5.62, 38.34	30.14, 42.28	-6.90, 14.54

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 7b-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		35		30	
	Missing, n (%)	10 (12.5)		6 (14.6)		9 (23.1)	
	BLOQ, n (%)	70 (100.0)		35 (100.0)		30 (100.0)	
	Geometric Mean (CV%)	6.43 (0.000)		6.43 (0.000)		6.43 (0.000)	
	95% CI of Geometric Mean	NC, NC		NC, NC		NC, NC	
	Median	6.43		6.43		6.43	
	Q25, Q75	6.43, 6.43		6.43, 6.43		6.43, 6.43	
	Min, Max	6.4, 6.4		6.4, 6.4		6.4, 6.4	
	Mean (SD)	6.43 (0.000)		6.43 (0.000)		6.43 (0.000)	
	95% CI of Mean	NC, NC		NC, NC		NC, NC	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 7b-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge	n	70	70	35	35	30	30
Confinement	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	70 (100.0)		35 (100.0)		29 (96.7)	
	Geometric Mean (CV%)	6.43 (0.000)		6.43 (0.000)		6.72 (24.777)	
	95% CI of Geometric Mean	NC, NC		NC, NC		6.13, 7.37	
	Median	6.43	0.00	6.43	0.00	6.43	0.00
	Q25, Q75	6.43, 6.43	0.00, 0.00	6.43, 6.43	0.00, 0.00	6.43, 6.43	0.00, 0.00
	Min, Max	6.4, 6.4	0.0, 0.0	6.4, 6.4	0.0, 0.0	6.4, 24.5	0.0, 280.7
	Mean (SD)	6.43 (0.000)	0.00 (0.000)	6.43 (0.000)	0.00 (0.000)	7.03 (3.296)	9.36 (51.252)
	95% CI of Mean	NC, NC	NC, NC	NC, NC	NC, NC	5.80, 8.27	-9.79, 28.50

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 7b-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	35	35	30	30
	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	69 (98.6)		35 (100.0)		30 (100.0)	
	Geometric Mean (CV%)	6.51 (10.405)		6.43 (0.000)		6.43 (0.000)	
	95% CI of Geometric Mean	6.35, 6.68		NC, NC		NC, NC	
	Median	6.43	0.00	6.43	0.00	6.43	0.00
	Q25, Q75	6.43, 6.43	0.00, 0.00	6.43, 6.43	0.00, 0.00	6.43, 6.43	0.00, 0.00
	Min, Max	6.4, 15.3	0.0, 138.3	6.4, 6.4	0.0, 0.0	6.4, 6.4	0.0, 0.0
	Mean (SD)	6.56 (1.063)	1.98 (16.526)	6.43 (0.000)	0.00 (0.000)	6.43 (0.000)	0.00 (0.000)
	95% CI of Mean	6.30, 6.82	-1.97, 5.92	NC, NC	NC, NC	NC, NC	NC, NC

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 5b,6b-epoxycholestanol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		35		30	
	Missing, n (%)	10 (12.5)		6 (14.6)		9 (23.1)	
	BLOQ, n (%)	9 (12.9)		6 (17.1)		4 (13.3)	
	Geometric Mean (CV%)	55.62 (83.389)		46.29 (80.121)		59.06 (100.446)	
	95% CI of Geometric Mean	46.77, 66.15		36.34, 58.96		43.23, 80.68	
	Median	57.42		49.08		67.94	
	Q25, Q75	37.09, 100.53		29.13, 82.48		33.56, 101.73	
	Min, Max	13.4, 201.9		13.4, 173.3		13.4, 411.8	
	Mean (SD)	69.52 (42.897)		57.00 (34.546)		81.65 (76.508)	
	95% CI of Mean	59.28, 79.75		45.13, 68.87		53.08, 110.22	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 5b,6b-epoxycholestanol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge	n	70	70	35	35	30	30
Confinement	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	11 (15.7)		6 (17.1)		5 (16.7)	
	Geometric Mean (CV%)	52.29 (91.928)		45.15 (79.249)		58.96 (117.637)	
	95% CI of Geometric Mean	43.38, 63.02		35.52, 57.40		41.62, 83.51	
	Median	56.25	-1.58	44.08	0.17	59.36	0.00
	Q25, Q75	36.25, 86.70	-19.25, 12.48	33.01, 72.29	-9.14, 14.31	34.84, 109.35	-21.72, 29.37
	Min, Max	13.4, 441.5	-64.2, 145.0	13.4, 170.8	-72.7, 135.6	13.4, 390.7	-58.3, 179.6
	Mean (SD)	70.64 (67.113)	-0.23 (37.472)	56.02 (37.139)	4.32 (38.842)	88.44 (87.061)	7.97 (46.187)
	95% CI of Mean	54.63, 86.65	-9.17, 8.71	43.26, 68.78	-9.03, 17.67	55.93, 120.95	-9.28, 25.22

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 5b,6b-epoxycholestanol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	35	35	30	30
	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	9 (12.9)		5 (14.3)		4 (13.3)	
	Geometric Mean (CV%)	55.47 (88.709)		48.08 (72.215)		61.96 (96.143)	
	95% CI of Geometric Mean	46.25, 66.53		38.49, 60.07		45.80, 83.81	
	Median	58.08	0.00	55.22	0.00	68.31	1.64
	Q25, Q75	34.33, 98.59	-14.40, 18.22	36.53, 77.38	-11.44, 24.05	40.67, 114.52	-13.71, 41.59
	Min, Max	13.4, 321.2	-73.3, 159.9	13.4, 144.1	-39.6, 152.1	13.4, 260.4	-68.0, 262.2
	Mean (SD)	72.27 (55.658)	7.30 (43.670)	57.30 (31.876)	8.42 (35.597)	81.48 (59.018)	18.88 (68.058)
	95% CI of Mean	59.00, 85.55	-3.12, 17.72	46.35, 68.26	-3.81, 20.65	59.44, 103.52	-6.54, 44.30

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 24(R)-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		35		30	
	Missing, n (%)	10 (12.5)		6 (14.6)		9 (23.1)	
	Geometric Mean (CV%)	47.70 (27.470)		49.73 (33.604)		49.10 (25.176)	
	95% CI of Geometric Mean	44.72, 50.87		44.44, 55.65		44.75, 53.86	
	Median	47.61		50.97		48.84	
	Q25, Q75	39.98, 54.84		39.46, 62.98		43.64, 53.26	
	Min, Max	22.7, 103.9		22.7, 108.0		26.0, 82.2	
	Mean (SD)	49.47 (14.033)		52.36 (17.417)		50.56 (12.628)	
	95% CI of Mean	46.12, 52.82		46.37, 58.35		45.84, 55.28	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 24(R)-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge	n	70	70	35	35	30	30
Confinement	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	Geometric Mean (CV%)	46.60 (26.886)		46.65 (31.370)		47.87 (35.706)	
	95% CI of Geometric Mean	43.75, 49.63		41.99, 51.83		42.05, 54.48	
	Median	45.52	-1.56	48.18	-6.47	48.51	0.55
	Q25, Q75	38.70, 54.85	-10.77, 4.39	39.31, 55.40	-12.21, 1.11	42.64, 62.93	-10.99, 8.62
	Min, Max	21.8, 108.5	-26.9, 44.9	23.8, 101.0	-25.5, 18.4	12.5, 73.5	-52.2, 36.0
	Mean (SD)	48.27 (13.620)	-1.56 (12.486)	48.83 (15.514)	-5.58 (10.895)	50.25 (14.135)	-0.89 (17.065)
	95% CI of Mean	45.02, 51.52	-4.54, 1.42	43.50, 54.17	-9.33, -1.83	44.96, 55.53	-7.27, 5.48

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 24(R)-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	35	35	30	30
	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	Geometric Mean (CV%)	47.96 (27.953)		49.17 (30.648)		48.54 (25.961)	
	95% CI of Geometric Mean	44.92, 51.20		44.35, 54.50		44.12, 53.40	
	Median	46.88	1.02	46.93	-0.69	48.70	-1.53
	Q25, Q75	39.64, 56.21	-7.06, 8.62	40.60, 60.37	-8.49, 5.14	42.69, 58.68	-10.95, 9.11
	Min, Max	26.4, 103.7	-33.7, 69.0	26.5, 98.8	-25.0, 29.1	27.9, 77.8	-20.5, 38.0
	Mean (SD)	49.84 (14.753)	1.77 (16.201)	51.41 (16.271)	-0.47 (11.642)	50.02 (12.081)	-0.34 (13.123)
	95% CI of Mean	46.32, 53.36	-2.10, 5.63	45.82, 57.01	-4.48, 3.53	45.51, 54.54	-5.24, 4.57

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 25-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		35		30	
	Missing, n (%)	10 (12.5)		6 (14.6)		9 (23.1)	
	BLOQ, n (%)	11 (15.7)		4 (11.4)		3 (10.0)	
	Geometric Mean (CV%)	5.78 (46.323)		5.87 (41.529)		5.82 (36.817)	
	95% CI of Geometric Mean	5.20, 6.42		5.11, 6.73		5.09, 6.65	
	Median	6.37		6.12		6.15	
	Q25, Q75	5.17, 7.50		5.59, 6.78		5.39, 7.34	
	Min, Max	2.4, 12.6		2.4, 14.2		2.4, 9.5	
	Mean (SD)	6.28 (2.310)		6.29 (2.310)		6.13 (1.766)	
	95% CI of Mean	5.72, 6.83		5.49, 7.09		5.47, 6.79	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 25-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge	n	70	70	35	35	30	30
Confinement	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	13 (18.6)		4 (11.4)		7 (23.3)	
	Geometric Mean (CV%)	5.23 (44.407)		5.48 (37.307)		5.07 (48.487)	
	95% CI of Geometric Mean	4.72, 5.79		4.84, 6.21		4.26, 6.02	
	Median	5.78	-6.70	5.67	-7.67	5.78	-0.66
	Q25, Q75	4.85, 7.02	-16.81, 0.97	5.00, 6.72	-16.52, 1.47	4.90, 7.03	-14.30, 2.15
	Min, Max	2.4, 10.7	-61.0, 162.6	2.4, 11.0	-55.6, 103.4	2.4, 9.6	-66.1, 25.9
	Mean (SD)	5.65 (1.987)	-5.34 (32.759)	5.80 (1.805)	-4.32 (23.054)	5.54 (2.085)	-9.10 (22.494)
	95% CI of Mean	5.17, 6.13	-13.15, 2.48	5.17, 6.42	-12.24, 3.61	4.75, 6.32	-17.50, -0.69

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 25-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	35	35	30	30
	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	10 (14.3)		4 (11.4)		3 (10.0)	
	Geometric Mean (CV%)	5.70 (43.576)		5.86 (41.859)		5.89 (39.861)	
	95% CI of Geometric Mean	5.16, 6.30		5.10, 6.73		5.10, 6.80	
	Median	6.11	-0.64	6.00	1.10	6.10	-0.10
	Q25, Q75	5.13, 7.24	-12.74, 10.59	5.29, 7.31	-7.04, 11.27	5.00, 7.41	-7.96, 13.07
	Min, Max	2.4, 12.1	-65.7, 185.1	2.4, 13.9	-60.9, 123.4	2.4, 13.0	-62.2, 105.1
	Mean (SD)	6.14 (2.144)	7.07 (47.694)	6.29 (2.314)	4.53 (34.048)	6.28 (2.152)	5.17 (30.151)
	95% CI of Mean	5.62, 6.66	-4.31, 18.44	5.49, 7.09	-7.17, 16.23	5.47, 7.09	-6.09, 16.43

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 22(R)-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		35		30	
	Missing, n (%)	10 (12.5)		6 (14.6)		9 (23.1)	
	BLOQ, n (%)	70 (100.0)		35 (100.0)		30 (100.0)	
	Geometric Mean (CV%)	4.73 (0.000)		4.73 (0.000)		4.73 (0.000)	
	95% CI of Geometric Mean	NC, NC		NC, NC		NC, NC	
	Median	4.73		4.73		4.73	
	Q25, Q75	4.73, 4.73		4.73, 4.73		4.73, 4.73	
	Min, Max	4.7, 4.7		4.7, 4.7		4.7, 4.7	
	Mean (SD)	4.73 (0.000)		4.73 (0.000)		4.73 (0.000)	
	95% CI of Mean	NC, NC		NC, NC		NC, NC	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 22(R)-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge	n	70	70	35	35	30	30
Confinement	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	70 (100.0)		35 (100.0)		30 (100.0)	
	Geometric Mean (CV%)	4.73 (0.000)		4.73 (0.000)		4.73 (0.000)	
	95% CI of Geometric Mean	NC, NC		NC, NC		NC, NC	
	Median	4.73	0.00	4.73	0.00	4.73	0.00
	Q25, Q75	4.73, 4.73	0.00, 0.00	4.73, 4.73	0.00, 0.00	4.73, 4.73	0.00, 0.00
	Min, Max	4.7, 4.7	0.0, 0.0	4.7, 4.7	0.0, 0.0	4.7, 4.7	0.0, 0.0
	Mean (SD)	4.73 (0.000)	0.00 (0.000)	4.73 (0.000)	0.00 (0.000)	4.73 (0.000)	0.00 (0.000)
	95% CI of Mean	NC, NC	NC, NC	NC, NC	NC, NC	NC, NC	NC, NC

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 22(R)-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	35	35	30	30
	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	70 (100.0)		35 (100.0)		30 (100.0)	
	Geometric Mean (CV%)	4.73 (0.000)		4.73 (0.000)		4.73 (0.000)	
	95% CI of Geometric Mean	NC, NC		NC, NC		NC, NC	
	Median	4.73	0.00	4.73	0.00	4.73	0.00
	Q25, Q75	4.73, 4.73	0.00, 0.00	4.73, 4.73	0.00, 0.00	4.73, 4.73	0.00, 0.00
	Min, Max	4.7, 4.7	0.0, 0.0	4.7, 4.7	0.0, 0.0	4.7, 4.7	0.0, 0.0
	Mean (SD)	4.73 (0.000)	0.00 (0.000)	4.73 (0.000)	0.00 (0.000)	4.73 (0.000)	0.00 (0.000)
	95% CI of Mean	NC, NC	NC, NC	NC, NC	NC, NC	NC, NC	NC, NC

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 4b-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		35		30	
	Missing, n (%)	10 (12.5)		6 (14.6)		9 (23.1)	
	BLOQ, n (%)	2 (2.9)		1 (2.9)		1 (3.3)	
	Geometric Mean (CV%)	21.58 (45.117)		19.87 (47.396)		22.34 (52.620)	
	95% CI of Geometric Mean	19.47, 23.92		17.01, 23.19		18.57, 26.87	
	Median	21.74		20.59		20.99	
	Q25, Q75	16.94, 26.88		13.92, 27.30		16.57, 31.25	
	Min, Max	5.3, 57.2		5.3, 46.4		5.3, 76.7	
	Mean (SD)	23.57 (10.382)		21.78 (9.283)		25.10 (13.342)	
	95% CI of Mean	21.09, 26.05		18.59, 24.98		20.11, 30.08	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 4b-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge	n	70	70	35	35	30	30
Confinement	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	3 (4.3)		2 (5.7)		2 (6.7)	
	Geometric Mean (CV%)	18.71 (44.853)		17.27 (46.787)		18.82 (52.462)	
	95% CI of Geometric Mean	16.89, 20.73		14.82, 20.13		15.65, 22.63	
	Median	19.01	-11.65	18.52	-11.93	19.21	-10.66
	Q25, Q75	14.90, 23.35	-24.74, 0.72	13.42, 25.24	-25.10, -0.79	15.60, 24.34	-22.09, 1.41
	Min, Max	5.3, 48.9	-64.7, 27.8	5.3, 36.4	-57.1, 125.7	5.3, 68.5	-59.0, 26.3
	Mean (SD)	20.40 (8.775)	-11.24 (18.497)	18.84 (7.475)	-8.83 (31.273)	21.07 (11.187)	-12.69 (21.912)
	95% CI of Mean	18.30, 22.49	-15.66, -6.83	16.26, 21.41	-19.58, 1.92	16.89, 25.25	-20.88, -4.50

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 4b-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	35	35	30	30
	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	3 (4.3)		4 (11.4)		2 (6.7)	
	Geometric Mean (CV%)	19.91 (49.955)		17.39 (61.789)		20.32 (58.517)	
	95% CI of Geometric Mean	17.78, 22.28		14.30, 21.14		16.59, 24.89	
	Median	19.55	-10.51	17.13	-6.96	19.27	-9.46
	Q25, Q75	14.81, 26.91	-20.13, 5.56	12.42, 25.36	-18.55, 3.52	15.30, 28.15	-23.96, 8.36
	Min, Max	5.3, 51.1	-64.7, 88.5	5.3, 50.3	-61.7, 38.0	5.3, 68.1	-52.8, 72.4
	Mean (SD)	22.07 (10.096)	-4.83 (24.397)	20.00 (10.260)	-9.12 (23.166)	23.36 (13.769)	-5.46 (27.126)
	95% CI of Mean	19.66, 24.48	-10.65, 0.99	16.47, 23.53	-17.08, -1.16	18.21, 28.51	-15.60, 4.67

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 27-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		35		30	
	Missing, n (%)	10 (12.5)		6 (14.6)		9 (23.1)	
	Geometric Mean (CV%)	134.28 (31.734)		145.56 (37.642)		147.20 (27.368)	
	95% CI of Geometric Mean	124.72, 144.58		128.44, 164.95		133.14, 162.74	
	Median	129.47		139.61		147.72	
	Q25, Q75	111.96, 164.79		117.94, 173.13		116.98, 184.71	
	Min, Max	65.3, 311.3		62.0, 421.3		82.6, 247.2	
	Mean (SD)	140.95 (46.791)		156.23 (68.756)		152.37 (40.558)	
	95% CI of Mean	129.79, 152.12		132.61, 179.85		137.22, 167.52	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 27-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge	n	70	70	35	35	30	30
Confinement	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	Geometric Mean (CV%)	126.05 (28.044)		132.93 (38.109)		139.38 (35.178)	
	95% CI of Geometric Mean	118.04, 134.60		117.13, 150.86		122.69, 158.35	
	Median	124.87	-5.50	138.29	-9.85	145.95	-2.46
	Q25, Q75	105.94, 155.62	-12.33, 0.42	107.65, 162.97	-17.52, 3.41	115.53, 182.02	-8.65, 0.56
	Min, Max	69.6, 256.8	-33.5, 21.2	45.3, 300.7	-31.9, 21.1	38.3, 230.2	-53.7, 28.2
	Mean (SD)	130.95 (37.794)	-5.53 (10.615)	141.67 (51.983)	-7.79 (12.990)	146.19 (40.827)	-3.80 (15.859)
	95% CI of Mean	121.93, 139.96	-8.06, -2.99	123.81, 159.53	-12.26, -3.32	130.94, 161.44	-9.72, 2.13

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): 27-hydroxycholesterol (ng/mL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	35	35	30	30
	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	Geometric Mean (CV%)	135.65 (31.926)		148.15 (39.330)		148.42 (30.311)	
	95% CI of Geometric Mean	125.94, 146.12		130.05, 168.77		132.86, 165.80	
	Median	136.75	2.44	140.97	2.21	155.38	-0.90
	Q25, Q75	108.95, 165.51	-9.02, 9.32	119.68, 187.20	-7.20, 10.74	114.11, 181.60	-10.41, 10.25
	Min, Max	59.1, 308.9	-34.9, 64.8	57.5, 408.2	-28.4, 34.9	85.6, 273.8	-27.6, 60.7
	Mean (SD)	142.26 (45.107)	2.34 (16.890)	159.47 (68.792)	2.74 (14.185)	154.76 (45.397)	2.25 (18.183)
	95% CI of Mean	131.50, 153.02	-1.69, 6.37	135.84, 183.11	-2.14, 7.62	137.81, 171.72	-4.55, 9.04

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): Cholesterol (mg/dL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	70		35		30	
	Missing, n (%)	10 (12.5)		6 (14.6)		9 (23.1)	
	Geometric Mean (CV%)	140.20 (24.775)		139.05 (27.810)		146.16 (20.811)	
	95% CI of Geometric Mean	132.27, 148.60		126.60, 152.73		135.34, 157.84	
	Median	142.50		135.00		153.00	
	Q25, Q75	115.00, 165.00		118.00, 169.00		123.00, 169.00	
	Min, Max	80.0, 231.0		78.0, 282.0		102.0, 223.0	
	Mean (SD)	144.36 (35.328)		144.37 (42.337)		149.17 (30.634)	
	95% CI of Mean	135.93, 152.79		129.82, 158.92		137.72, 160.61	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): Cholesterol (mg/dL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge	n	70	70	35	35	30	30
Confinement	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	BLOQ, n (%)	0		0		1 (3.3)	
	Geometric Mean (CV%)	131.54 (22.212)		123.45 (26.777)		133.61 (41.767)	
	95% CI of Geometric Mean	124.83, 138.61		112.77, 135.13		115.03, 155.20	
	Median	132.50	-6.75	126.00	-11.48	139.00	-5.02
	Q25, Q75	114.00, 153.00	-15.48, 2.65	99.00, 153.00	-21.21, -2.68	106.00, 166.00	-18.29, 7.79
	Min, Max	80.0, 200.0	-35.5, 65.0	69.0, 201.0	-30.6, 15.7	25.0, 241.0	-75.5, 33.3
	Mean (SD)	134.66 (29.165)	-5.06 (15.432)	127.57 (32.778)	-10.37 (12.647)	141.90 (42.542)	-5.16 (22.077)
	95% CI of Mean	127.70, 141.62	-8.74, -1.37	116.31, 138.84	-14.72, -6.02	126.01, 157.79	-13.41, 3.09

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.66.2 Descriptive Statistics of Oxysterol Parameters - FAS****Parameter (units): Cholesterol (mg/dL)**

Timepoint	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 90	n	70	70	35	35	30	30
	Missing, n (%)	10 (12.5)	10 (12.5)	6 (14.6)	6 (14.6)	9 (23.1)	9 (23.1)
	Geometric Mean (CV%)	139.51 (25.495)		138.76 (25.300)		147.10 (30.210)	
	95% CI of Geometric Mean	131.40, 148.11		127.37, 151.16		131.73, 164.27	
	Median	138.00	-0.69	131.00	-1.36	157.00	0.71
	Q25, Q75	116.00, 167.00	-11.45, 12.00	120.00, 166.00	-7.58, 9.17	120.00, 188.00	-9.87, 14.29
	Min, Max	84.0, 255.0	-31.4, 36.3	88.0, 241.0	-20.2, 23.0	87.0, 281.0	-27.2, 60.8
	Mean (SD)	143.91 (36.616)	0.75 (15.964)	143.14 (37.811)	0.48 (11.928)	153.33 (44.861)	2.37 (19.804)
	95% CI of Mean	135.18, 152.65	-3.06, 4.57	130.15, 156.14	-3.63, 4.58	136.58, 170.09	-5.03, 9.77

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THSm2.2 arms or the last assessment prior to 10AM on Day 1 in the SA arm.

Note: 'Missing' percentages are based on the number of subjects indicated in the column header (N), while 'BLOQ' percentages are based on the number of subjects being summarized (n).

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
THSm2.2	Period 2	n	9	40	2	27	78
		Mean (SD)	13.25 (6.719)	10.46 (6.996)	NC	12.64 (7.501)	11.68 (7.103)
		95% CI	8.08, 18.42	8.22, 12.71	NC	9.67, 15.62	10.07, 13.29
		Median	14.62	9.54	NC	11.27	10.19
		Min, Max	3.1, 21.3	0.1, 35.5	NC	1.2, 35.8	0.1, 35.8
	Period 3	n	9	39	2	27	77
		Mean (SD)	11.20 (8.132)	11.29 (7.640)	NC	15.55 (11.061)	12.90 (9.090)
		95% CI	4.94, 17.45	8.81, 13.77	NC	11.17, 19.93	10.83, 14.97
		Median	11.87	10.18	NC	12.57	11.60
		Min, Max	0.0, 20.7	0.1, 33.5	NC	4.0, 58.0	0.0, 58.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
THSm2.2	Period 4	n	9	38	2	25	74
		Mean (SD)	10.51 (9.044)	11.64 (7.532)	NC	12.68 (6.089)	12.02 (7.195)
		95% CI	3.55, 17.47	9.16, 14.12	NC	10.16, 15.20	10.35, 13.69
		Median	11.97	11.00	NC	13.62	11.19
		Min, Max	0.0, 21.2	0.0, 30.2	NC	2.3, 24.4	0.0, 30.2
	Ambulatory	n	9	40	2	27	78
		Mean (SD)	11.65 (7.414)	10.95 (7.235)	NC	14.25 (8.358)	12.32 (7.672)
		95% CI	5.95, 17.36	8.63, 13.27	NC	10.94, 17.56	10.58, 14.05
		Median	12.55	10.05	NC	12.19	11.11
		Min, Max	2.1, 21.1	0.1, 33.0	NC	3.4, 38.5	0.1, 38.5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
mCC/CC	Period 2	n	23	79	2	46	150
		Mean (SD)	4.46 (7.291)	5.37 (7.253)	NC	4.32 (6.492)	4.84 (6.977)
		95% CI	1.31, 7.62	3.74, 7.00	NC	2.39, 6.25	3.71, 5.97
		Median	0.35	1.08	NC	0.92	0.81
		Min, Max	0.0, 22.9	0.0, 31.0	NC	0.0, 26.5	0.0, 31.0
	Period 3	n	21	76	2	45	144
		Mean (SD)	5.44 (8.008)	5.49 (7.269)	NC	4.09 (6.639)	4.97 (7.142)
		95% CI	1.79, 9.09	3.83, 7.16	NC	2.09, 6.09	3.79, 6.15
		Median	1.10	0.89	NC	0.77	0.75
		Min, Max	0.0, 26.7	0.0, 28.2	NC	0.0, 29.6	0.0, 29.6

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
mCC/CC	Period 4	n	21	74	2	42	139
		Mean (SD)	5.33 (7.962)	5.27 (7.220)	NC	4.48 (7.141)	4.96 (7.239)
		95% CI	1.70, 8.96	3.59, 6.95	NC	2.25, 6.71	3.75, 6.18
		Median	0.22	0.80	NC	0.50	0.48
		Min, Max	0.0, 23.0	0.0, 30.2	NC	0.0, 32.4	0.0, 32.4
	Ambulatory	n	23	79	2	46	150
		Mean (SD)	4.92 (7.388)	6.15 (9.022)	NC	4.38 (6.669)	5.33 (8.071)
		95% CI	1.72, 8.12	4.12, 8.17	NC	2.39, 6.36	4.03, 6.64
		Median	0.76	1.14	NC	1.38	0.93
		Min, Max	0.0, 24.3	0.0, 44.5	NC	0.0, 29.4	0.0, 44.5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
Inhaler	Period 2	n	23	79	2	46	150
		Mean (SD)	0.11 (0.514)	0.00 (0.000)	NC	0.00 (0.000)	0.02 (0.201)
		95% CI	-0.12, 0.33	NC, NC	NC	NC, NC	-0.02, 0.05
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 2.5	0.0, 0.0	NC	0.0, 0.0	0.0, 2.5
	Period 3	n	21	76	2	45	144
		Mean (SD)	0.38 (1.723)	0.01 (0.100)	NC	0.00 (0.000)	0.06 (0.662)
		95% CI	-0.40, 1.17	-0.02, 0.04	NC	NC, NC	-0.05, 0.18
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 7.9	0.0, 0.9	NC	0.0, 0.0	0.0, 7.9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
Inhaler	Period 4	n	21	74	2	42	139
		Mean (SD)	0.54 (1.945)	0.07 (0.582)	NC	0.00 (0.000)	0.12 (0.872)
		95% CI	-0.35, 1.43	-0.07, 0.21	NC	NC, NC	-0.03, 0.27
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 8.7	0.0, 5.0	NC	0.0, 0.0	0.0, 8.7
	Ambulatory	n	23	79	2	46	150
		Mean (SD)	0.32 (1.360)	0.03 (0.227)	NC	0.00 (0.000)	0.06 (0.559)
		95% CI	-0.27, 0.92	-0.03, 0.08	NC	NC, NC	-0.03, 0.16
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 6.5	0.0, 2.0	NC	0.0, 0.0	0.0, 6.5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
Gums	Period 2	n	23	79	2	46	150
		Mean (SD)	0.01 (0.033)	0.00 (0.009)	NC	0.00 (0.000)	0.00 (0.015)
		95% CI	-0.01, 0.03	-0.01, 0.01	NC	NC, NC	-0.01, 0.01
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.2	0.0, 0.1	NC	0.0, 0.0	0.0, 0.2
	Period 3	n	21	76	2	45	144
		Mean (SD)	0.05 (0.233)	0.00 (0.000)	NC	0.00 (0.000)	0.01 (0.089)
		95% CI	-0.06, 0.16	NC, NC	NC	NC, NC	-0.01, 0.03
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 1.1	0.0, 0.0	NC	0.0, 0.0	0.0, 1.1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
Gums	Period 4	n	21	74	2	42	139
		Mean (SD)	0.07 (0.324)	0.00 (0.000)	NC	0.00 (0.000)	0.01 (0.126)
		95% CI	-0.08, 0.22	NC, NC	NC	NC, NC	-0.02, 0.04
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 1.5	0.0, 0.0	NC	0.0, 0.0	0.0, 1.5
	Ambulatory	n	23	79	2	46	150
		Mean (SD)	0.04 (0.194)	0.00 (0.003)	NC	0.00 (0.000)	0.01 (0.076)
		95% CI	-0.05, 0.13	-0.01, 0.01	NC	NC, NC	-0.01, 0.02
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.9	0.0, 0.0	NC	0.0, 0.0	0.0, 0.9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
Lozenges	Period 2	n	23	79	2	46	150
		Mean (SD)	0.00 (0.000)	0.00 (0.035)	NC	0.02 (0.148)	0.01 (0.086)
		95% CI	NC, NC	-0.01, 0.02	NC	-0.03, 0.07	-0.01, 0.03
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.3	NC	0.0, 1.0	0.0, 1.0
	Period 3	n	21	76	2	45	144
		Mean (SD)	0.00 (0.000)	0.01 (0.050)	NC	0.00 (0.000)	0.00 (0.037)
		95% CI	NC, NC	-0.01, 0.02	NC	NC, NC	-0.01, 0.01
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.4	NC	0.0, 0.0	0.0, 0.4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
Lozenges	Period 4	n	21	74	2	42	139
		Mean (SD)	0.00 (0.000)	0.01 (0.045)	NC	0.00 (0.000)	0.00 (0.033)
		95% CI	NC, NC	-0.01, 0.02	NC	NC, NC	-0.01, 0.01
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.4	NC	0.0, 0.0	0.0, 0.4
	Ambulatory	n	23	79	2	46	150
		Mean (SD)	0.00 (0.000)	0.00 (0.043)	NC	0.01 (0.052)	0.00 (0.042)
		95% CI	NC, NC	-0.01, 0.02	NC	-0.01, 0.03	-0.01, 0.02
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.4	NC	0.0, 0.3	0.0, 0.4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
Patches	Period 2	n	23	79	2	46	150
		Mean (SD)	0.00 (0.000)	0.01 (0.096)	NC	0.01 (0.069)	0.01 (0.079)
		95% CI	NC, NC	-0.02, 0.04	NC	-0.02, 0.04	-0.01, 0.03
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.8	NC	0.0, 0.5	0.0, 0.8
	Period 3	n	21	76	2	45	144
		Mean (SD)	0.05 (0.219)	0.00 (0.043)	NC	0.03 (0.202)	0.02 (0.143)
		95% CI	-0.06, 0.15	-0.01, 0.02	NC	-0.04, 0.10	-0.01, 0.05
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 1.0	0.0, 0.4	NC	0.0, 1.4	0.0, 1.4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
Patches	Period 4	n	21	74	2	42	139
		Mean (SD)	0.06 (0.271)	0.01 (0.109)	NC	0.01 (0.070)	0.02 (0.137)
		95% CI	-0.07, 0.19	-0.02, 0.04	NC	-0.02, 0.04	-0.01, 0.05
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 1.2	0.0, 0.9	NC	0.0, 0.4	0.0, 1.2
	Ambulatory	n	23	79	2	46	150
		Mean (SD)	0.03 (0.162)	0.01 (0.080)	NC	0.02 (0.103)	0.02 (0.103)
		95% CI	-0.04, 0.11	-0.01, 0.03	NC	-0.02, 0.05	-0.01, 0.04
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.8	0.0, 0.7	NC	0.0, 0.7	0.0, 0.8

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
Cigar/Cigarillo	Period 2	n	23	79	2	46	150
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC	NC, NC	NC, NC
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC	0.0, 0.0	0.0, 0.0
	Period 3	n	21	76	2	45	144
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC	NC, NC	NC, NC
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
Cigar/Cigarillo	Period 4	n	21	74	2	42	139
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC	0.00 (0.016)	0.00 (0.009)
		95% CI	NC, NC	NC, NC	NC	-0.01, 0.01	-0.01, 0.01
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC	0.0, 0.1	0.0, 0.1
	Ambulatory	n	23	79	2	46	150
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC	0.00 (0.006)	0.00 (0.003)
		95% CI	NC, NC	NC, NC	NC	-0.01, 0.01	-0.01, 0.01
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
Tob. Not Listed	Period 2	n	23	79	2	46	150
		Mean (SD)	0.10 (0.339)	0.00 (0.016)	NC	0.00 (0.023)	0.02 (0.136)
		95% CI	-0.06, 0.25	-0.01, 0.01	NC	-0.01, 0.02	-0.01, 0.04
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 1.5	0.0, 0.1	NC	0.0, 0.2	0.0, 1.5
	Period 3	n	21	76	2	45	144
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC	NC, NC	NC, NC
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC	0.0, 0.0	0.0, 0.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
Tob. Not Listed	Period 4	n	21	74	2	42	139
		Mean (SD)	0.00 (0.000)	0.00 (0.000)	NC	0.00 (0.000)	0.00 (0.000)
		95% CI	NC, NC	NC, NC	NC	NC, NC	NC, NC
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 0.0	NC	0.0, 0.0	0.0, 0.0
	Ambulatory	n	23	79	2	46	150
		Mean (SD)	0.03 (0.104)	0.00 (0.006)	NC	0.00 (0.007)	0.01 (0.042)
		95% CI	-0.02, 0.08	-0.01, 0.01	NC	-0.01, 0.01	-0.01, 0.02
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.5	0.0, 0.0	NC	0.0, 0.0	0.0, 0.5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
E-Cigarette	Period 2	n	23	79	2	46	150
		Mean (SD)	0.66 (2.326)	0.04 (0.321)	NC	0.09 (0.590)	0.15 (1.004)
		95% CI	-0.35, 1.67	-0.04, 0.11	NC	-0.09, 0.27	-0.02, 0.32
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 10.6	0.0, 2.8	NC	0.0, 4.0	0.0, 10.6
	Period 3	n	21	76	2	45	144
		Mean (SD)	0.16 (0.476)	0.07 (0.448)	NC	0.11 (0.525)	0.09 (0.472)
		95% CI	-0.06, 0.38	-0.04, 0.17	NC	-0.06, 0.27	0.01, 0.17
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 2.1	0.0, 3.7	NC	0.0, 3.2	0.0, 3.7

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.67 Descriptive Statistics of Average Daily Product Use in Ambulatory Period by Preferred Product Declared at Admission - FAS**

Product	Period	Statistic	Product Preference				Overall
			THSm2.2	mCC	SA	No preference	
E-Cigarette	Period 4	n	21	74	2	42	139
		Mean (SD)	0.00 (0.000)	0.04 (0.283)	NC	0.04 (0.243)	0.03 (0.245)
		95% CI	NC, NC	-0.03, 0.11	NC	-0.04, 0.12	-0.01, 0.08
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 0.0	0.0, 2.4	NC	0.0, 1.6	0.0, 2.4
	Ambulatory	n	23	79	2	46	150
		Mean (SD)	0.25 (0.815)	0.05 (0.279)	NC	0.08 (0.385)	0.09 (0.434)
		95% CI	-0.10, 0.61	-0.01, 0.12	NC	-0.04, 0.20	0.02, 0.17
		Median	0.00	0.00	NC	0.00	0.00
		Min, Max	0.0, 3.5	0.0, 2.2	NC	0.0, 2.4	0.0, 3.5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Tob. Not Listed refers to other tobacco products not previously listed.

Note: NC = Not calculated.

Note: No recorded product use for other nicotine/tobacco products.

**Table 15.2.4.68 Descriptive Statistics of Product Use Categories by Preferred Product Declared at Admission - FAS**

Product Use Categorization	Product preference			
	THSm2.2 n (%)	mCC n (%)	SA n (%)	No preference n (%)
THSm2.2 Arm	10	40	2	27
THSm2.2 ([70-100]%)	8 (80.0)	27 (67.5)	2 (100.0)	26 (96.3)
Primarily THSm2.2 ([95-100]%)	7 (70.0)	23 (57.5)	2 (100.0)	14 (51.9)
Exclusively THSm2.2 (100%)	3 (30.0)	16 (40.0)	1 (50.0)	7 (25.9)
Predominantly THSm2.2 ([70-95]%)	1 (10.0)	4 (10.0)	0	12 (44.4)
Dual ([30-70]%)	1 (10.0)	8 (20.0)	0	1 (3.7)
Dual mostly THSm2.2 ([60-70]%)	0	1 (2.5)	0	0
Dual balanced ([40-60]%)	1 (10.0)	5 (12.5)	0	1 (3.7)
Dual mostly CC ([30-40]%)	0	2 (5.0)	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Ambulatory Safety column refers to product use categorization over the whole ambulatory period based on missing imputation rules for safety summaries.

**Table 15.2.4.68 Descriptive Statistics of Product Use Categories by Preferred Product Declared at Admission - FAS**

Product Use Categorization	Product preference			
	THSm2.2 n (%)	mCC n (%)	SA n (%)	No preference n (%)
CC ([0-30]%)	0	3 (7.5)	0	0
Predominantly CC ([5-30]%)	0	2 (5.0)	0	0
Primarily CC ([0-5]%)	0	1 (2.5)	0	0
Discontinued in previous period	1 (10.0)	2 (5.0)	0	0
mCC Arm	5	25	0	11
CC Only	4(80.0)	22 (88.0)	0	10 (90.9)
CC Dual	0	1 (4.0)	0	0
Discontinued in previous period	1(20.0)	2 (8.0)	0	1 (9.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Ambulatory Safety column refers to product use categorization over the whole ambulatory period based on missing imputation rules for safety summaries.

**Table 15.2.4.68 Descriptive Statistics of Product Use Categories by Preferred Product Declared at Admission - FAS**

Product Use Categorization	Product preference			
	THSm2.2 n (%)	mCC n (%)	SA n (%)	No preference n (%)
SA Arm	11	19	0	9
Not Abstinent	8 (72.7)	11 (57.9)	0	6 (66.7)
Predominantly Abstinent	0	1 (5.3)	0	1 (11.1)
Abstinent	2 (18.2)	3 (15.8)	0	1 (11.1)
Discontinued in previous period	1 (9.1)	4 (21.1)	0	1 (11.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System.

Note: Ambulatory periods defined as Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Ambulatory Safety column refers to product use categorization over the whole ambulatory period based on missing imputation rules for safety summaries.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units): Diffusion Capacity for Lung CO (mL/min/mmHg)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	72		34		21	
	Missing, n (%)	3 (4.0)		1 (2.9)		3 (12.5)	
	Mean (SD)	23.355 (5.9669)		24.274 (6.2069)		23.118 (6.1072)	
	95% CI	21.952, 24.758		22.108, 26.440		20.338, 25.899	
	Median	23.815		24.770		25.060	
	Q25, Q75	18.470, 27.750		20.560, 28.380		17.360, 28.720	
	Min, Max	12.79, 36.66		12.20, 46.10		11.41, 32.94	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units): Diffusion Capacity for Lung CO (mL/min/mmHg)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	73	71	34	34	23	21
	Missing, n (%)	2 (2.7)	4 (5.3)	1 (2.9)	1 (2.9)	1 (4.2)	3 (12.5)
	Mean (SD)	23.510 (6.0436)	0.165 (2.0212)	23.700 (6.0541)	-0.574 (2.3208)	23.023 (6.2634)	-0.002 (2.1855)
	95% CI	22.099, 24.920	-0.314, 0.644	21.587, 25.813	-1.385, 0.236	20.314, 25.732	-0.998, 0.993
	Median	22.770	0.200	24.665	-0.490	22.840	0.020
	Q25, Q75	18.910, 27.520	-1.100, 1.410	19.050, 27.330	-2.040, 0.810	16.880, 27.920	-1.690, 1.270
	Min, Max	12.36, 40.14	-5.77, 4.64	12.98, 42.99	-7.89, 4.51	12.31, 34.21	-3.67, 5.10

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units): Diffusion Capacity for Lung CO (mL/min/mmHg)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		8	
	Missing, n (%)	0		0		1 (11.1)	
	Mean (SD)	23.100 (6.4674)		24.704 (6.2673)		26.720 (5.4249)	
	95% CI	21.200, 24.999		22.444, 26.964		22.184, 31.256	
	Median	22.330		24.900		28.045	
	Q25, Q75	17.480, 27.740		20.975, 28.625		24.720, 30.175	
	Min, Max	12.79, 36.66		12.20, 46.10		15.20, 32.68	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set**

Parameter (units): Diffusion Capacity for Lung CO (mL/min/mmHg)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	46	46	31	31	9	8
	Missing, n (%)	1 (2.1)	1 (2.1)	1 (3.1)	1 (3.1)	0	1 (11.1)
	Mean (SD)	23.747 (6.2397)	0.572 (2.5619)	25.075 (6.7355)	0.264 (3.1016)	23.909 (7.1276)	-1.499 (4.4027)
	95% CI	21.893, 25.600	-0.189, 1.333	22.603, 27.546	-0.875, 1.402	18.430, 29.388	-5.180, 2.182
	Median	23.655	0.775	24.070	-0.410	26.140	-2.050
	Q25, Q75	17.700, 27.560	-1.150, 2.080	19.830, 28.900	-2.600, 2.720	19.160, 29.400	-3.965, 1.785
	Min, Max	11.20, 38.74	-5.17, 7.00	13.94, 42.01	-4.99, 6.77	12.92, 31.99	-8.28, 4.75

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Rate Constant of CO (mmol/min/kPa/L)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	72		34		21	
	Missing, n (%)	3 (4.0)		1 (2.9)		3 (12.5)	
	Mean (SD)	1.381 (0.2625)		1.338 (0.2442)		1.351 (0.2926)	
	95% CI	1.319, 1.443		1.252, 1.424		1.217, 1.485	
	Median	1.355		1.290		1.320	
	Q25, Q75	1.195, 1.565		1.160, 1.510		1.240, 1.550	
	Min, Max	0.75, 2.01		0.93, 1.95		0.79, 2.05	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Rate Constant of CO (mmol/min/kPa/L)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	73	71	34	34	23	21
	Missing, n (%)	2 (2.7)	4 (5.3)	1 (2.9)	1 (2.9)	1 (4.2)	3 (12.5)
	Mean (SD)	1.378 (0.2510)	-0.001 (0.1042)	1.324 (0.2599)	-0.014 (0.1198)	1.369 (0.2778)	-0.001 (0.1375)
	95% CI	1.319, 1.437	-0.026, 0.024	1.232, 1.415	-0.057, 0.028	1.249, 1.490	-0.064, 0.062
	Median	1.380	-0.010	1.375	-0.005	1.370	0.020
	Q25, Q75	1.210, 1.570	-0.070, 0.040	1.150, 1.490	-0.100, 0.060	1.190, 1.550	-0.050, 0.080
	Min, Max	0.75, 2.05	-0.23, 0.32	0.72, 1.80	-0.25, 0.24	0.81, 1.93	-0.29, 0.25

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Rate Constant of CO (mmol/min/kPa/L)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		8	
	Missing, n (%)	0		0		1 (11.1)	
	Mean (SD)	1.382 (0.2837)		1.372 (0.2571)		1.379 (0.3609)	
	95% CI	1.298, 1.466		1.279, 1.465		1.077, 1.681	
	Median	1.380		1.350		1.310	
	Q25, Q75	1.190, 1.560		1.175, 1.550		1.155, 1.585	
	Min, Max	0.75, 2.01		0.99, 1.95		0.88, 2.05	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Rate Constant of CO (mmol/min/kPa/L)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	46	46	31	31	9	8
	Missing, n (%)	1 (2.1)	1 (2.1)	1 (3.1)	1 (3.1)	0	1 (11.1)
	Mean (SD)	1.418 (0.3190)	0.037 (0.1475)	1.371 (0.2535)	0.000 (0.1353)	1.329 (0.3228)	-0.029 (0.1954)
	95% CI	1.323, 1.513	-0.008, 0.081	1.277, 1.464	-0.050, 0.050	1.080, 1.577	-0.193, 0.135
	Median	1.405	0.020	1.410	0.000	1.300	-0.020
	Q25, Q75	1.270, 1.540	-0.060, 0.110	1.220, 1.530	-0.100, 0.100	1.160, 1.640	-0.190, 0.090
	Min, Max	0.71, 2.41	-0.23, 0.53	0.83, 2.02	-0.27, 0.27	0.81, 1.77	-0.28, 0.29

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set**

Parameter (units): Best measured FEV1 value (with bronchodilator) (L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Mean (SD)	3.392 (0.8541)		3.626 (0.7809)		3.260 (0.8490)	
	95% CI	3.195, 3.589		3.358, 3.895		2.901, 3.619	
	Median	3.410		3.710		3.315	
	Q25, Q75	2.680, 4.030		3.050, 4.270		2.480, 3.895	
	Min, Max	1.83, 5.18		2.05, 5.10		1.90, 4.85	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units): Best measured FEV1 value (with bronchodilator) (L)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Mean (SD)	3.404 (0.8838)	0.018 (0.1981)	3.649 (0.7341)	-0.024 (0.2024)	3.362 (0.8961)	0.137 (0.2022)
	95% CI	3.198, 3.609	-0.028, 0.065	3.392, 3.905	-0.095, 0.048	2.974, 3.750	0.049, 0.225
	Median	3.430	0.035	3.730	-0.070	3.510	0.100
	Q25, Q75	2.830, 4.070	-0.040, 0.120	3.020, 4.150	-0.130, 0.070	2.630, 3.920	-0.010, 0.320
	Min, Max	0.96, 5.24	-1.00, 0.42	1.98, 5.10	-0.42, 0.54	2.07, 5.04	-0.20, 0.54

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units): Best measured FEV1 value (with bronchodilator) (L)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	3.404 (0.9653)		3.678 (0.7234)		3.602 (0.8632)	
	95% CI	3.121, 3.688		3.417, 3.939		2.938, 4.266	
	Median	3.220		3.745		3.670	
	Q25, Q75	2.630, 4.220		3.100, 4.265		3.270, 4.120	
	Min, Max	1.83, 5.18		2.05, 5.10		1.90, 4.85	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units): Best measured FEV1 value (with bronchodilator) (L)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	31	31	9	9
	Missing, n (%)	0	0	1 (3.1)	1 (3.1)	0	0
	Mean (SD)	3.352 (0.9667)	-0.052 (0.1740)	3.571 (0.6994)	-0.115 (0.1569)	3.522 (0.9013)	-0.080 (0.4374)
	95% CI	3.068, 3.636	-0.104, -0.001	3.314, 3.828	-0.173, -0.057	2.829, 4.216	-0.417, 0.257
	Median	3.350	-0.050	3.710	-0.120	3.750	-0.040
	Q25, Q75	2.620, 4.110	-0.150, 0.090	3.050, 4.150	-0.200, -0.010	2.780, 3.890	-0.170, 0.220
	Min, Max	1.57, 5.25	-0.45, 0.32	2.04, 4.89	-0.60, 0.12	2.12, 5.12	-1.02, 0.48

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units): Best measured FVC value (with bronchodilator) (L)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Mean (SD)	4.277 (1.0935)		4.614 (0.9210)		4.122 (1.0511)	
	95% CI	4.025, 4.529		4.297, 4.931		3.677, 4.566	
	Median	4.280		4.760		4.040	
	Q25, Q75	3.370, 5.090		3.950, 5.170		3.275, 4.885	
	Min, Max	2.23, 6.41		2.38, 6.35		2.45, 5.99	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units): Best measured FVC value (with bronchodilator) (L)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Mean (SD)	4.296 (1.0727)	0.024 (0.1957)	4.652 (0.8468)	-0.016 (0.1853)	4.143 (1.0437)	0.091 (0.1953)
	95% CI	4.047, 4.545	-0.022, 0.070	4.356, 4.948	-0.081, 0.049	3.691, 4.594	0.006, 0.176
	Median	4.315	0.020	4.670	-0.030	3.850	0.090
	Q25, Q75	3.560, 5.050	-0.080, 0.150	4.030, 5.170	-0.080, 0.060	3.500, 4.790	-0.070, 0.230
	Min, Max	2.22, 6.43	-0.69, 0.55	2.35, 6.32	-0.48, 0.43	2.59, 6.13	-0.32, 0.46

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units): Best measured FVC value (with bronchodilator) (L)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	4.262 (1.1856)		4.639 (0.8386)		4.577 (1.0256)	
	95% CI	3.914, 4.611		4.336, 4.942		3.788, 5.366	
	Median	4.220		4.785		4.850	
	Q25, Q75	3.320, 5.140		4.010, 5.135		4.190, 4.950	
	Min, Max	2.23, 6.41		2.38, 6.29		2.45, 5.99	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units): Best measured FVC value (with bronchodilator) (L)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	31	31	9	9
	Missing, n (%)	0	0	1 (3.1)	1 (3.1)	0	0
	Mean (SD)	4.219 (1.1926)	-0.043 (0.1988)	4.556 (0.8309)	-0.108 (0.1864)	4.489 (1.0103)	-0.088 (0.1991)
	95% CI	3.869, 4.570	-0.102, 0.016	4.251, 4.861	-0.177, -0.039	3.712, 5.266	-0.241, 0.066
	Median	4.240	-0.050	4.640	-0.110	4.670	-0.050
	Q25, Q75	3.340, 5.160	-0.150, 0.120	3.950, 5.070	-0.180, 0.020	4.140, 4.800	-0.110, -0.020
	Min, Max	2.10, 6.31	-0.53, 0.36	2.27, 6.04	-0.63, 0.32	2.55, 6.19	-0.48, 0.20

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set**

Parameter (units):Vital Capacity (L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		34		23	
	Missing, n (%)	1 (1.3)		1 (2.9)		1 (4.2)	
	Mean (SD)	4.340 (1.0734)		4.716 (0.8909)		4.113 (1.0226)	
	95% CI	4.090, 4.589		4.405, 5.027		3.670, 4.555	
	Median	4.365		4.810		4.000	
	Q25, Q75	3.520, 5.080		4.000, 5.220		3.320, 4.790	
	Min, Max	2.37, 6.44		2.39, 6.35		2.45, 6.09	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set**

Parameter (units):Vital Capacity (L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Mean (SD)	4.392 (1.0605)	0.052 (0.1984)	4.682 (0.8653)	-0.034 (0.1445)	4.185 (1.0215)	0.073 (0.2579)
	95% CI	4.145, 4.638	0.006, 0.098	4.379, 4.984	-0.085, 0.017	3.743, 4.627	-0.039, 0.185
	Median	4.325	0.020	4.805	-0.030	4.160	0.100
	Q25, Q75	3.610, 5.190	-0.060, 0.150	3.980, 5.230	-0.100, 0.090	3.600, 4.910	-0.020, 0.260
	Min, Max	2.31, 6.43	-0.31, 0.79	2.35, 6.38	-0.35, 0.24	2.62, 6.08	-0.81, 0.44

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set**

Parameter (units):Vital Capacity (L)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	4.315 (1.1716)		4.684 (0.8614)		4.670 (0.9994)	
	95% CI	3.970, 4.659		4.373, 4.995		3.901, 5.439	
	Median	4.130		4.810		4.760	
	Q25, Q75	3.520, 5.220		4.010, 5.220		4.560, 4.920	
	Min, Max	2.37, 6.44		2.39, 6.29		2.45, 6.09	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set**

Parameter (units):Vital Capacity (L)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	31	31	9	9
	Missing, n (%)	0	0	1 (3.1)	1 (3.1)	0	0
	Mean (SD)	4.266 (1.1782)	-0.049 (0.1748)	4.558 (0.8488)	-0.150 (0.1782)	4.569 (1.0315)	-0.101 (0.3839)
	95% CI	3.919, 4.612	-0.101, 0.003	4.246, 4.870	-0.216, -0.084	3.776, 5.362	-0.397, 0.194
	Median	4.240	-0.070	4.610	-0.170	4.760	-0.080
	Q25, Q75	3.420, 5.250	-0.140, 0.080	3.890, 5.110	-0.270, -0.040	4.060, 4.980	-0.250, 0.170
	Min, Max	2.36, 6.27	-0.45, 0.40	2.24, 6.24	-0.61, 0.24	2.62, 6.28	-0.91, 0.42

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set**

Parameter (units): Total Lung Capacity (L)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		34		23	
	Missing, n (%)	1 (1.3)		1 (2.9)		1 (4.2)	
	Mean (SD)	5.910 (1.7472)		6.154 (1.0996)		5.959 (1.3254)	
	95% CI	5.504, 6.315		5.770, 6.539		5.386, 6.533	
	Median	5.915		6.205		5.750	
	Q25, Q75	4.770, 6.940		5.580, 6.900		5.050, 7.030	
	Min, Max	2.74, 13.07		3.19, 8.21		3.65, 8.94	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Total Lung Capacity (L)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Mean (SD)	6.000 (1.4805)	0.091 (1.1996)	6.226 (1.2521)	0.072 (1.1672)	6.127 (2.0232)	0.167 (2.2138)
	95% CI	5.657, 6.344	-0.188, 0.369	5.789, 6.664	-0.336, 0.480	5.251, 7.002	-0.790, 1.125
	Median	5.905	0.145	6.295	-0.025	5.530	-0.120
	Q25, Q75	5.160, 6.790	-0.160, 0.290	5.590, 7.040	-0.430, 0.250	4.950, 6.870	-0.260, 0.160
	Min, Max	2.35, 11.02	-5.98, 4.72	3.22, 10.49	-2.16, 5.74	3.86, 13.90	-3.41, 9.67

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units): Total Lung Capacity (L)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	5.727 (1.8693)		6.185 (1.1224)		6.607 (1.4133)	
	95% CI	5.178, 6.276		5.780, 6.590		5.520, 7.693	
	Median	5.690		6.210		6.840	
	Q25, Q75	4.550, 6.940		5.420, 6.930		5.860, 7.030	
	Min, Max	2.74, 13.07		3.19, 8.21		4.23, 8.94	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Total Lung Capacity (L)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	31	31	9	9
	Missing, n (%)	0	0	1 (3.1)	1 (3.1)	0	0
	Mean (SD)	5.704 (1.5126)	-0.023 (0.9252)	5.926 (1.0316)	-0.299 (0.6602)	5.969 (1.1645)	-0.638 (1.7277)
	95% CI	5.260, 6.149	-0.295, 0.249	5.547, 6.305	-0.542, -0.057	5.073, 6.864	-1.966, 0.691
	Median	5.900	0.070	6.100	-0.120	5.830	-0.130
	Q25, Q75	4.810, 6.540	-0.180, 0.310	5.310, 6.580	-0.450, 0.100	5.350, 6.680	-0.350, -0.010
	Min, Max	2.78, 9.00	-4.07, 2.03	3.05, 7.56	-2.56, 0.64	4.36, 8.00	-4.49, 1.60

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Residual Volume (L)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		34		23	
	Missing, n (%)	1 (1.3)		1 (2.9)		1 (4.2)	
	Mean (SD)	3.024 (1.1955)		3.161 (0.9274)		2.943 (0.7053)	
	95% CI	2.747, 3.302		2.837, 3.485		2.638, 3.248	
	Median	2.825		3.240		2.980	
	Q25, Q75	2.340, 3.380		2.420, 3.550		2.590, 3.300	
	Min, Max	1.41, 8.77		1.72, 6.04		1.24, 4.38	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Residual Volume (L)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Mean (SD)	2.895 (1.0014)	-0.129 (1.1107)	3.173 (1.0150)	0.012 (0.8687)	3.136 (2.0679)	0.193 (2.1224)
	95% CI	2.663, 3.128	-0.387, 0.129	2.818, 3.528	-0.292, 0.316	2.241, 4.031	-0.725, 1.111
	Median	2.810	-0.045	3.140	-0.015	2.750	-0.220
	Q25, Q75	2.370, 3.280	-0.390, 0.170	2.650, 3.660	-0.210, 0.300	2.280, 3.230	-0.390, 0.070
	Min, Max	1.24, 8.19	-6.40, 4.81	1.57, 7.28	-2.99, 3.01	1.64, 12.15	-1.34, 9.76

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Residual Volume (L)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	2.987 (1.1696)		3.123 (0.9227)		3.233 (0.5045)	
	95% CI	2.644, 3.331		2.790, 3.456		2.845, 3.622	
	Median	2.820		3.190		3.110	
	Q25, Q75	2.260, 3.440		2.390, 3.500		2.980, 3.470	
	Min, Max	1.41, 8.77		1.72, 6.04		2.39, 3.93	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Residual Volume (L)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	31	31	9	9
	Missing, n (%)	0	0	1 (3.1)	1 (3.1)	0	0
	Mean (SD)	2.759 (0.7461)	-0.229 (0.7374)	2.953 (0.6974)	-0.202 (0.6286)	3.370 (0.4635)	0.137 (0.7420)
	95% CI	2.539, 2.978	-0.445, -0.012	2.697, 3.210	-0.433, 0.029	3.013, 3.727	-0.434, 0.707
	Median	2.680	-0.110	2.930	-0.110	3.150	0.040
	Q25, Q75	2.260, 3.150	-0.360, 0.110	2.370, 3.570	-0.440, 0.110	3.020, 3.590	-0.100, 0.120
	Min, Max	1.30, 5.06	-3.71, 0.89	1.80, 4.39	-2.89, 0.71	2.94, 4.26	-0.96, 1.87

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units): Inspiratory Capacity (L)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		34		23	
	Missing, n (%)	1 (1.3)		1 (2.9)		1 (4.2)	
	Mean (SD)	2.885 (0.9735)		2.994 (0.7940)		3.016 (0.9365)	
	95% CI	2.659, 3.111		2.716, 3.271		2.611, 3.422	
	Median	2.820		2.995		3.010	
	Q25, Q75	2.320, 3.590		2.580, 3.680		2.240, 3.420	
	Min, Max	0.49, 5.90		0.48, 4.33		1.84, 5.04	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Inspiratory Capacity (L)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Mean (SD)	3.105 (0.9080)	0.220 (0.6212)	3.053 (0.5924)	0.060 (0.5986)	2.990 (0.8763)	-0.026 (0.5476)
	95% CI	2.894, 3.316	0.075, 0.364	2.846, 3.260	-0.150, 0.269	2.611, 3.370	-0.263, 0.212
	Median	2.970	0.190	3.185	-0.020	2.890	0.020
	Q25, Q75	2.530, 3.730	-0.060, 0.450	2.700, 3.460	-0.190, 0.260	2.340, 3.530	-0.090, 0.220
	Min, Max	0.60, 5.45	-2.18, 2.12	1.49, 4.07	-1.00, 2.73	1.75, 5.12	-2.31, 0.53

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units): Inspiratory Capacity (L)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	2.740 (0.9989)		3.062 (0.6562)		3.373 (1.1047)	
	95% CI	2.446, 3.033		2.825, 3.299		2.524, 4.223	
	Median	2.700		2.995		3.100	
	Q25, Q75	2.000, 3.560		2.620, 3.520		2.820, 4.020	
	Min, Max	0.49, 5.11		1.43, 4.33		1.84, 5.04	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set**

Parameter (units):Inspiratory Capacity (L)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	31	31	9	9
	Missing, n (%)	0	0	1 (3.1)	1 (3.1)	0	0
	Mean (SD)	2.945 (1.0403)	0.206 (0.5561)	2.973 (0.8046)	-0.098 (0.5708)	2.599 (1.2653)	-0.774 (1.2550)
	95% CI	2.639, 3.251	0.042, 0.370	2.677, 3.269	-0.308, 0.112	1.626, 3.572	-1.740, 0.191
	Median	2.840	0.170	3.070	-0.030	2.640	-0.270
	Q25, Q75	2.290, 3.680	-0.080, 0.510	2.490, 3.640	-0.340, 0.160	1.570, 3.250	-0.430, -0.170
	Min, Max	0.49, 5.10	-1.16, 2.21	1.10, 4.35	-2.19, 0.90	0.77, 4.99	-3.53, 0.13

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Mid expiratory flow 25-75 (with bronchodilator) (L/s)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Mean (SD)	3.246 (1.1133)		3.334 (1.1182)		3.125 (1.0189)	
	95% CI	2.989, 3.502		2.949, 3.718		2.695, 3.556	
	Median	3.230		3.270		3.135	
	Q25, Q75	2.310, 4.090		2.690, 4.240		2.400, 4.030	
	Min, Max	0.96, 6.17		1.50, 5.13		1.56, 4.66	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Mid expiratory flow 25-75 (with bronchodilator) (L/s)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Mean (SD)	3.301 (1.2512)	0.067 (0.6168)	3.402 (1.0715)	0.014 (0.5524)	3.295 (1.2060)	0.155 (0.6444)
	95% CI	3.010, 3.591	-0.076, 0.210	3.027, 3.776	-0.179, 0.208	2.773, 3.817	-0.124, 0.434
	Median	3.180	0.045	3.725	0.000	3.350	0.130
	Q25, Q75	2.470, 3.980	-0.180, 0.360	2.640, 4.180	-0.370, 0.320	2.170, 4.530	-0.320, 0.550
	Min, Max	0.54, 6.89	-1.38, 3.28	0.51, 4.97	-1.18, 1.69	1.70, 5.33	-0.85, 1.79

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Mid expiratory flow 25-75 (with bronchodilator) (L/s)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	3.265 (1.2127)		3.486 (1.1223)		3.343 (1.0246)	
	95% CI	2.908, 3.621		3.081, 3.891		2.555, 4.131	
	Median	3.210		3.525		3.260	
	Q25, Q75	2.290, 4.160		2.985, 4.300		2.720, 4.180	
	Min, Max	0.96, 6.17		1.50, 5.13		1.62, 4.66	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Mid expiratory flow 25-75 (with bronchodilator) (L/s)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	31	31	9	9
	Missing, n (%)	0	0	1 (3.1)	1 (3.1)	0	0
	Mean (SD)	4.863 (11.8570)	1.599 (11.6780)	5.811 (13.8073)	2.369 (13.6315)	3.501 (1.4328)	0.158 (1.2713)
	95% CI	1.382, 8.345	-1.831, 5.028	0.746, 10.876	-2.632, 7.370	2.399, 4.603	-0.820, 1.135
	Median	2.840	-0.090	3.360	-0.010	3.000	-0.360
	Q25, Q75	2.240, 4.040	-0.400, 0.170	2.630, 4.400	-0.290, 0.330	2.310, 4.300	-0.490, 0.670
	Min, Max	1.18, 84.00	-1.37, 79.88	1.65, 80.00	-1.93, 75.76	2.06, 6.09	-0.86, 3.22

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set**

Parameter (units):Ratio between FEV1/FVC (Derived) (RATIO)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	74		34		23	
	Missing, n (%)	1 (1.3)		1 (2.9)		1 (4.2)	
	Mean (SD)	0.796 (0.0545)		0.788 (0.0652)		0.795 (0.0561)	
	95% CI	0.783, 0.809		0.764, 0.811		0.770, 0.820	
	Median	0.800		0.790		0.790	
	Q25, Q75	0.760, 0.840		0.750, 0.840		0.760, 0.830	
	Min, Max	0.66, 0.90		0.61, 0.91		0.68, 0.95	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Ratio between FEV1/FVC (Derived) (RATIO)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Mean (SD)	0.792 (0.0702)	-0.004 (0.0481)	0.786 (0.0727)	-0.002 (0.0308)	0.810 (0.0507)	0.015 (0.0363)
	95% CI	0.775, 0.809	-0.016, 0.008	0.760, 0.812	-0.013, 0.009	0.787, 0.832	-0.001, 0.031
	Median	0.800	0.000	0.800	0.000	0.810	0.010
	Q25, Q75	0.760, 0.840	-0.010, 0.020	0.760, 0.840	-0.020, 0.020	0.780, 0.830	-0.010, 0.020
	Min, Max	0.43, 0.90	-0.37, 0.04	0.53, 0.90	-0.08, 0.09	0.70, 0.94	-0.04, 0.12

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Ratio between FEV1/FVC (Derived) (RATIO)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	0.800 (0.0498)		0.794 (0.0685)		0.784 (0.0365)	
	95% CI	0.784, 0.815		0.769, 0.819		0.756, 0.813	
	Median	0.810		0.805		0.780	
	Q25, Q75	0.760, 0.840		0.760, 0.845		0.770, 0.800	
	Min, Max	0.66, 0.89		0.61, 0.91		0.73, 0.85	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Ratio between FEV1/FVC (Derived) (RATIO)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	31	31	9	9
	Missing, n (%)	0	0	1 (3.1)	1 (3.1)	0	0
	Mean (SD)	0.794 (0.0506)	-0.005 (0.0247)	0.785 (0.0684)	-0.006 (0.0335)	0.788 (0.0914)	0.003 (0.0770)
	95% CI	0.779, 0.810	-0.013, 0.002	0.760, 0.811	-0.019, 0.007	0.717, 0.858	-0.056, 0.063
	Median	0.800	0.000	0.790	0.000	0.800	0.000
	Q25, Q75	0.770, 0.820	-0.020, 0.010	0.740, 0.840	-0.020, 0.020	0.760, 0.830	-0.010, 0.050
	Min, Max	0.65, 0.90	-0.08, 0.04	0.65, 0.90	-0.11, 0.06	0.58, 0.91	-0.15, 0.13

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set**

Parameter (units):Percent of predicted FEV1 value (with bronchodilator) (%)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Mean (SD)	93.1 (12.50)		96.1 (14.04)		91.0 (12.65)	
	95% CI	90.1, 96.0		91.2, 101.0		85.6, 96.4	
	Median	94.0		94.0		92.0	
	Q25, Q75	84.0, 103.0		84.0, 110.0		82.5, 100.5	
	Min, Max	60, 122		71, 126		63, 110	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set**

Parameter (units):Percent of predicted FEV1 value (with bronchodilator) (%)
Product Use Time Period: Period 1

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Mean (SD)	92.9 (14.57)	-0.1 (7.32)	95.8 (14.39)	-0.6 (6.40)	94.0 (12.26)	3.0 (5.34)
	95% CI	89.5, 96.4	-1.8, 1.7	90.7, 100.8	-2.9, 1.7	88.6, 99.3	0.7, 5.4
	Median	96.0	1.0	94.5	-0.5	93.0	3.0
	Q25, Q75	86.0, 103.0	-1.0, 4.0	87.0, 106.0	-4.0, 2.0	89.0, 105.0	0.0, 6.0
	Min, Max	37, 123	-40, 16	66, 126	-24, 17	68, 116	-6, 14

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set**

Parameter (units):Percent of predicted FEV1 value (with bronchodilator) (%)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	92.7 (13.35)		96.5 (14.48)		95.7 (10.76)	
	95% CI	88.8, 96.7		91.2, 101.8		87.3, 104.0	
	Median	95.0		95.0		99.0	
	Q25, Q75	83.0, 103.0		84.0, 110.5		92.0, 102.0	
	Min, Max	60, 122		71, 126		78, 110	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set**

Parameter (units):Percent of predicted FEV1 value (with bronchodilator) (%)
Product Use Time Period: Period 4

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	31	31	9	9
	Missing, n (%)	0	0	1 (3.1)	1 (3.1)	0	0
	Mean (SD)	90.0 (14.43)	-2.8 (6.86)	92.6 (14.56)	-3.6 (5.15)	94.1 (10.11)	-1.6 (12.07)
	95% CI	85.7, 94.2	-4.9, -0.7	87.2, 98.0	-5.6, -1.7	86.3, 101.9	-10.9, 7.8
	Median	90.0	-2.0	89.0	-3.0	93.0	-1.0
	Q25, Q75	79.0, 101.0	-5.0, 2.0	81.0, 103.0	-5.0, 0.0	91.0, 99.0	-3.0, 5.0
	Min, Max	57, 119	-25, 9	68, 121	-18, 2	74, 107	-30, 12

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Percent of predicted FVC value (with bronchodilator) (%)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	75		35		24	
	Mean (SD)	94.2 (13.79)		99.5 (14.65)		91.9 (12.42)	
	95% CI	91.0, 97.4		94.4, 104.6		86.6, 97.2	
	Median	96.0		98.0		91.0	
	Q25, Q75	83.0, 104.0		87.0, 111.0		84.0, 102.0	
	Min, Max	62, 122		71, 128		64, 111	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Percent of predicted FVC value (with bronchodilator) (%)****Product Use Time Period: Period 1**

Timepoint	Statistic	THSm2.2 (N=75)		mCC (N=35)		SA (N=24)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 6/Discharge Confinement	n	74	74	34	34	23	23
	Missing, n (%)	1 (1.3)	1 (1.3)	1 (2.9)	1 (2.9)	1 (4.2)	1 (4.2)
	Mean (SD)	94.6 (14.27)	0.4 (5.33)	98.9 (14.43)	-1.0 (6.18)	93.2 (11.96)	1.8 (4.43)
	95% CI	91.3, 98.0	-0.9, 1.7	93.9, 104.0	-3.2, 1.2	88.0, 98.4	-0.2, 3.7
	Median	98.0	1.0	97.5	-1.0	92.0	1.0
	Q25, Q75	83.0, 105.0	-2.0, 4.0	90.0, 110.0	-2.0, 1.0	85.0, 104.0	-2.0, 4.0
	Min, Max	65, 126	-20, 15	70, 128	-30, 8	66, 115	-6, 14

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Percent of predicted FVC value (with bronchodilator) (%)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Baseline	n	47		32		9	
	Mean (SD)	93.7 (13.66)		99.1 (15.18)		97.3 (11.77)	
	95% CI	89.6, 97.7		93.6, 104.6		88.2, 106.4	
	Median	96.0		98.0		100.0	
	Q25, Q75	83.0, 104.0		86.5, 110.0		90.0, 106.0	
	Min, Max	62, 120		71, 128		79, 111	

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.70 Descriptive Statistics of Full Lung Function Results - PP Set****Parameter (units):Percent of predicted FVC value (with bronchodilator) (%)****Product Use Time Period: Period 4**

Timepoint	Statistic	THSm2.2 (N=47)		mCC (N=32)		SA (N=9)	
		Value	% Change(*)	Value	% Change(*)	Value	% Change(*)
Day 91/Discharge Ambulatory	n	47	47	31	31	9	9
	Missing, n (%)	0	0	1 (3.1)	1 (3.1)	0	0
	Mean (SD)	91.7 (14.51)	-1.9 (5.71)	96.6 (15.48)	-2.5 (4.68)	96.7 (11.37)	-0.7 (5.10)
	95% CI	87.4, 96.1	-3.7, -0.2	90.9, 102.3	-4.3, -0.8	87.9, 105.5	-4.6, 3.3
	Median	92.0	-1.0	95.0	-2.0	95.0	0.0
	Q25, Q75	79.0, 101.0	-4.0, 2.0	85.0, 112.0	-4.0, 0.0	88.0, 105.0	-2.0, 3.0
	Min, Max	61, 125	-22, 7	68, 123	-18, 6	81, 112	-11, 6

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: * % Change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10AM on Day 1 in the SA arm.

**Table 15.2.4.71 Analysis of Full Lung Function Results - PP Set****Parameter (units): Diffusion Capacity for Lung CO (mL/min/mmHg)**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 6/Discharge Confinement	n	71	34	21		
	LS Mean	23.69	23.08	23.53	0.61	0.16
	95% CI	23.19, 24.20	22.37, 23.79	22.62, 24.43	-0.25, 1.47	-0.85, 1.18
	p-value				0.080	
Day 91/Discharge Ambulatory	n	45	30	8		
	LS Mean	24.56	24.25	22.61	0.31	1.95
	95% CI	23.64, 25.48	23.17, 25.32	20.50, 24.73	-1.09, 1.72	-0.33, 4.22
	p-value				0.329	

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC are only presented for Diffusion Capacity for Lung CO and Rate Constant of CO.

**Table 15.2.4.71 Analysis of Full Lung Function Results - PP Set****Parameter (units):Rate Constant of CO (mmol/min/kPa/L)**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 6/Discharge Confinement	n	71	34	21		
	LS Mean	1.37	1.35	1.36	0.02	0.00
	95% CI	1.33, 1.40	1.31, 1.39	1.31, 1.42	-0.03, 0.07	-0.06, 0.06
	p-value				0.218	
Day 91/Discharge Ambulatory	n	45	30	7		
	LS Mean	1.41	1.36	1.38	0.05	0.04
	95% CI	1.36, 1.46	1.30, 1.42	1.26, 1.49	-0.02, 0.12	-0.09, 0.16
	p-value				0.081	

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC are only presented for Diffusion Capacity for Lung CO and Rate Constant of CO.

**Table 15.2.4.71 Analysis of Full Lung Function Results - PP Set****Parameter (units): Best measured FEV1 value (with bronchodilator) (L)**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 6/Discharge Confinement	n	74	34	23		
	LS Mean	3.44	3.41	3.56	0.03	-0.11
	95% CI	3.39, 3.50	3.34, 3.48	3.47, 3.65	-0.06, 0.12	-0.21, -0.02
Day 91/Discharge Ambulatory	n	47	30	9		
	LS Mean	3.45	3.41	3.43	0.05	0.02
	95% CI	3.38, 3.52	3.32, 3.49	3.28, 3.58	-0.06, 0.15	-0.14, 0.18

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC are only presented for Diffusion Capacity for Lung CO and Rate Constant of CO.

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**Table 15.2.4.71 Analysis of Full Lung Function Results - PP Set****Parameter (units): Best measured FVC value (with bronchodilator) (L)**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 6/Discharge Confinement	n	74	34	23		
	LS Mean	4.34	4.34	4.39	0.01	-0.05
	95% CI	4.29, 4.39	4.27, 4.40	4.31, 4.48	-0.08, 0.09	-0.14, 0.04
Day 91/Discharge Ambulatory	n	47	30	9		
	LS Mean	4.37	4.32	4.34	0.05	0.04
	95% CI	4.31, 4.44	4.25, 4.40	4.20, 4.47	-0.05, 0.15	-0.11, 0.19

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC are only presented for Diffusion Capacity for Lung CO and Rate Constant of CO.

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**Table 15.2.4.71 Analysis of Full Lung Function Results - PP Set****Parameter (units):Vital Capacity (L)**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 6/Discharge Confinement	n	74	34	23		
	LS Mean	4.43	4.38	4.43	0.05	0.00
	95% CI	4.38, 4.48	4.31, 4.45	4.35, 4.51	-0.03, 0.13	-0.09, 0.09
Day 91/Discharge Ambulatory	n	47	30	9		
	LS Mean	4.43	4.33	4.38	0.10	0.05
	95% CI	4.36, 4.50	4.25, 4.41	4.23, 4.52	0.00, 0.21	-0.10, 0.21

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC are only presented for Diffusion Capacity for Lung CO and Rate Constant of CO.

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**Table 15.2.4.71 Analysis of Full Lung Function Results - PP Set****Parameter (units):Total Lung Capacity (L)**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 6/Discharge Confinement	n	74	34	23		
	LS Mean	5.95	6.07	6.05	-0.12	-0.10
	95% CI	5.65, 6.24	5.64, 6.49	5.53, 6.56	-0.63, 0.39	-0.69, 0.48
Day 91/Discharge Ambulatory	n	47	30	9		
	LS Mean	5.78	5.69	5.38	0.09	0.39
	95% CI	5.56, 5.99	5.43, 5.95	4.90, 5.87	-0.25, 0.43	-0.13, 0.92

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC are only presented for Diffusion Capacity for Lung CO and Rate Constant of CO.

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**Table 15.2.4.71 Analysis of Full Lung Function Results - PP Set****Parameter (units):Residual Volume (L)**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 6/Discharge Confinement	n	74	34	23		
	LS Mean	2.89	3.1	3.16	-0.21	-0.28
	95% CI	2.61, 3.16	2.69, 3.50	2.67, 3.65	-0.69, 0.27	-0.83, 0.28
Day 91/Discharge Ambulatory	n	47	30	9		
	LS Mean	2.8	2.89	3.21	-0.09	-0.42
	95% CI	2.66, 2.94	2.71, 3.06	2.90, 3.53	-0.31, 0.13	-0.76, -0.07

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC are only presented for Diffusion Capacity for Lung CO and Rate Constant of CO.

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**Table 15.2.4.71 Analysis of Full Lung Function Results - PP Set****Parameter (units):Inspiratory Capacity (L)**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 6/Discharge Confinement	n	74	34	23		
	LS Mean	3.07	2.98	2.89	0.10	0.19
	95% CI	2.96, 3.19	2.81, 3.14	2.68, 3.09	-0.10, 0.30	-0.04, 0.42
Day 91/Discharge Ambulatory	n	47	30	9		
	LS Mean	3.01	2.79	2.13	0.21	0.88
	95% CI	2.82, 3.19	2.57, 3.02	1.72, 2.54	-0.08, 0.51	0.43, 1.33

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC are only presented for Diffusion Capacity for Lung CO and Rate Constant of CO.

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**Table 15.2.4.71 Analysis of Full Lung Function Results - PP Set****Parameter (units):Mid expiratory flow 25-75 (with bronchodilator) (L/s)**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 6/Discharge Confinement	n	74	34	23		
	LS Mean	3.32	3.28	3.4	0.04	-0.08
	95% CI	3.17, 3.47	3.07, 3.49	3.14, 3.66	-0.21, 0.30	-0.37, 0.21
Day 91/Discharge Ambulatory	n	47	30	9		
	LS Mean	5.21	5.88	3.99	-0.67	1.23
	95% CI	1.62, 8.81	1.45, 10.31	-4.20, 12.17	-6.33, 4.99	-7.62, 10.07

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC are only presented for Diffusion Capacity for Lung CO and Rate Constant of CO.

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**Table 15.2.4.71 Analysis of Full Lung Function Results - PP Set****Parameter (units):Ratio between FEV1/FVC (Derived) (RATIO)**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 6/Discharge Confinement	n	74	34	23		
	LS Mean	0.79	0.79	0.81	0.00	-0.02
	95% CI	0.77, 0.80	0.77, 0.81	0.79, 0.83	-0.02, 0.02	-0.04, 0.01
Day 91/Discharge Ambulatory	n	47	30	9		
	LS Mean	0.79	0.79	0.8	0.00	-0.01
	95% CI	0.77, 0.81	0.77, 0.81	0.77, 0.83	-0.02, 0.02	-0.04, 0.02

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC are only presented for Diffusion Capacity for Lung CO and Rate Constant of CO.

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**Table 15.2.4.71 Analysis of Full Lung Function Results - PP Set****Parameter (units):Percent of predicted FEV1 value (with bronchodilator) (%)**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 6/Discharge Confinement	n	74	34	23		
	LS Mean	93.22	92.9	96.27	0.32	-3.05
	95% CI	91.64, 94.80	90.58, 95.21	93.47, 99.08	-2.46, 3.10	-6.24, 0.13
Day 91/Discharge Ambulatory	n	47	30	9		
	LS Mean	91.18	90.64	92.64	0.53	-1.46
	95% CI	89.08, 93.27	88.05, 93.24	87.87, 97.41	-2.79, 3.85	-6.63, 3.71

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC are only presented for Diffusion Capacity for Lung CO and Rate Constant of CO.

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**Table 15.2.4.71 Analysis of Full Lung Function Results - PP Set****Parameter (units):Percent of predicted FVC value (with bronchodilator) (%)**

Variable	Statistic	THSm2.2	mCC	SA	THSm2.2 - mCC Difference	THSm2.2 - SA Difference
Day 6/Discharge Confinement	n	74	34	23		
	LS Mean	95.46	94.5	96.68	0.97	-1.22
	95% CI	94.21, 96.72	92.65, 96.35	94.45, 98.91	-1.26, 3.19	-3.75, 1.31
Day 91/Discharge Ambulatory	n	47	30	9		
	LS Mean	93.81	93.36	95.07	0.46	-1.26
	95% CI	92.22, 95.41	91.37, 95.34	91.45, 98.70	-2.09, 3.00	-5.20, 2.68

Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an Mixed model conducted with baseline value, study arm, sex and mCC consumption reported at screening as fixed effect factors.

Note: mCC =Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: p-value for one-sided test for comparison between THSm2.2 and mCC are only presented for Diffusion Capacity for Lung CO and Rate Constant of CO.

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15.2.5 Compliance



Table 15.2.5.1
Summary of Compliance as Measured by Exhaled CO (ppm) During Confinement Period - FAS in the SA Arm

Timepoint	Statistic	SA (N=39)			
		08:00 AM-09:30 AM	12:00 PM-01:30 PM	04:00 PM-05:30 PM	08:00 PM-09:30 PM
Day 2	n	34	34	34	34
	n (%) ≤ 10 ppm	34 (100.0)	33 (97.1)	34 (100.0)	34 (100.0)
	n (%) > 10 ppm	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)
Day 3	n	34	34	34	34
	n (%) ≤ 10 ppm	34 (100.0)	34 (100.0)	34 (100.0)	34 (100.0)
	n (%) > 10 ppm	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Note: SA = Smoking abstinence.

Note: Percentages are based on the number of subjects with available data at each timepoint (n)

* Day 6 CO breath test was done prior to discharge irrespective of product use.

Appendix 15.3.3.2

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Status: Final

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Table 15.2.5.1
Summary of Compliance as Measured by Exhaled CO (ppm) During Confinement Period - FAS in the SA Arm

Timepoint	Statistic	SA (N=39)			
		08:00 AM-09:30 AM	12:00 PM-01:30 PM	04:00 PM-05:30 PM	08:00 PM-09:30 PM
Day 4	n	34	34	34	34
	n (%) ≤ 10 ppm	34 (100.0)	34 (100.0)	34 (100.0)	34 (100.0)
	n (%) > 10 ppm	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Day 5	n	34	34	34	34
	n (%) ≤ 10 ppm	34 (100.0)	34 (100.0)	34 (100.0)	34 (100.0)
	n (%) > 10 ppm	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Day 6/Discharge Confinement*	n	32			
	n (%) ≤ 10 ppm	27 (84.4)			
	n (%) > 10 ppm	5 (15.6)			

Note: SA = Smoking abstinence.

Note: Percentages are based on the number of subjects with available data at each timepoint (n)

* Day 6 CO breath test was done prior to discharge irrespective of product use.

**Table 15.2.5.2 Summary of Compliance by Period and Overall - FAS**

Period	Confinement	Ambulatory			Overall FAS
	Period 1	Period 2	Period 3	Period 4	
THSm2.2 - N	80	80	80	80	80
Exclusive product use ⁽¹⁾ - n(%)					
Yes	75 (93.8)	32 (40.0)	36 (45.0)	41 (51.3)	24 (30.0)
No	5 (6.3)	48 (60.0)	44 (55.0)	39 (48.8)	56 (70.0)
PP criterion ⁽²⁾ - n(%)					
Yes	80 (100.0)	42 (52.5)	42 (52.5)	50 (62.5)	35 (43.8)
No	0 (0.0)	38 (47.5)	38 (47.5)	30 (37.5)	45 (56.3)
mCC - N	41	41	41	41	41
Exclusive product use ⁽¹⁾ - n(%)					
Yes	35 (85.4)	34 (82.9)	34 (82.9)	31 (75.6)	29 (70.7)
No	6 (14.6)	7 (17.1)	7 (17.1)	10 (24.4)	12 (29.3)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

[1]: No use of any nicotine or tobacco-containing product other than the assigned product. However, in the SA arm, NRT use is allowed during the study.

In the SA arm, 100% abstinence also requires CO breath test ≤ 10 ppm (apart from at Day 1). (Criterion for compliant population)

[2]: No use of more than 2 CC during a single day within any time period and no use of on average more than 0.5 CC per day over the exposure period.

Note: Percentages are based on the number of subjects (N) in the FAS for each arm and period (first row of each arm).

**Table 15.2.5.2 Summary of Compliance by Period and Overall - FAS**

Period	Confinement	Ambulatory			Overall FAS
	Period 1	Period 2	Period 3	Period 4	
SA - N	39	39	39	39	39
Abstinent ⁽¹⁾ - n(%)					
Yes	24 (61.5)	8 (20.5)	7 (18.0)	7 (18.0)	5 (12.8)
No	15 (38.5)	31 (79.5)	32 (82.1)	32 (82.1)	34 (87.2)
PP criterion ⁽²⁾ - n(%)					
Yes	28 (71.8)	15 (38.5)	14 (35.9)	11 (28.2)	8 (20.5)
No	11 (28.2)	24 (61.5)	25 (64.1)	28 (71.8)	31 (79.5)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

[1]: No use of any nicotine or tobacco-containing product other than the assigned product. However, in the SA arm, NRT use is allowed during the study. In the SA arm, 100% abstinence also requires CO breath test ≤ 10 ppm (apart from at Day 1). (Criterion for compliant population)

[2]: No use of more than 2 CC during a single day within any time period and no use of on average more than 0.5 CC per day over the exposure period.

Note: Percentages are based on the number of subjects (N) in the FAS for each arm and period (first row of each arm).



15.2.6 Safety Summary Tables

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Pre-Randomization**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events (AE)	33 (41.3)	38	11 (26.8)	16	14 (35.9)	18	4 (80.0)	12	62 (37.6)	84
AE Serious										
Yes("SAE")	0		0		0		1 (20.0)	2	1 (0.6)	2
No("AE")	33 (41.3)	38	11 (26.8)	16	14 (35.9)	18	4 (80.0)	10	62 (37.6)	82
AE related to IP										
Not related	33 (41.3)	37	11 (26.8)	16	14 (35.9)	18	4 (80.0)	12	62 (37.6)	83
Related	1 (1.3)	1	0		0		0		1 (0.6)	1
Expected	1 (1.3)	1	0		0		0		1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized.

Note: The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Pre-Randomization**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Not expected	0		0		0		0		0	
AE related to study procedure										
Not related	28 (35.0)	30	9 (22.0)	12	11 (28.2)	15	2 (40.0)	7	50 (30.3)	64
Related	5 (6.3)	8	3 (7.3)	4	3 (7.7)	3	2 (40.0)	5	13 (7.9)	20
AE severity										
Mild	27 (33.8)	31	8 (19.5)	12	11 (28.2)	15	3 (60.0)	8	49 (29.7)	66
Moderate	7 (8.8)	7	4 (9.8)	4	3 (7.7)	3	1 (20.0)	1	15 (9.1)	15
Severe	0		0		0		2 (40.0)	3	2 (1.2)	3

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized.

Note: The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Pre-Randomization**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Action taken due to AE										
Action taken with study product										
Product use interrupted	0		0		0		1 (20.0)	1	1 (0.6)	1
Product use stopped	0		0		0		1 (20.0)	1	1 (0.6)	1
Product use reduced	0		0		0		0		0	
Not applicable	0		0		13 (33.3)	17	1 (20.0)	1	14 (8.5)	18
None	33 (41.3)	38	11 (26.8)	16	1 (2.6)	1	3 (60.0)	9	48 (29.1)	64
Treatment given										

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized.

Note: The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Pre-Randomization**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Yes	0		1 (2.4)	1	1 (2.6)	1	1 (20.0)	2	3 (1.8)	4
No	33 (41.3)	38	10 (24.4)	15	13 (33.3)	17	4 (80.0)	10	60 (36.4)	80
Other action taken										
Crushed Ice To Sooth Irritated Throat	0		0		1 (2.6)	1	0		1 (0.6)	1
Subject Discontinued From Study	0		0		0		1 (20.0)	1	1 (0.6)	1
Subject Was Discontinued From Study	0		0		0		1 (20.0)	1	1 (0.6)	1
Repeat Labs Done	0		1 (2.4)	1	0		0		1 (0.6)	1
Vital Signs Taken	1 (1.3)	1	0		0		0		1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized.

Note: The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Pre-Randomization**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Treatment Given Was To Lay The Subject Down No Medication Given	1 (1.3)	1	0		0		0		1 (0.6)	1
Vital Signs, Blood Sugar And O2 Saturation Subject Discontinued From Study	0		0		0		1 (20.0)	1	1 (0.6)	1
No action taken due to AE	32 (40.0)	36	9 (22.0)	14	0		3 (60.0)	7	44 (26.7)	57

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized.

Note: The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Post-Randomization**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events (AE)	52 (65.0)	114	20 (48.8)	32	23 (59.0)	49	95 (59.4)	195
AE Serious								
Yes("SAE")	0		0		0		0	
No("AE")	52 (65.0)	114	20 (48.8)	32	23 (59.0)	49	95 (59.4)	195
AE related to IP								
Not related	52 (65.0)	107	19 (46.3)	31	23 (59.0)	49	94 (58.8)	187
Related	7 (8.8)	7	1 (2.4)	1	0		8 (5.0)	8
Expected	0		1 (2.4)	1	0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Post-Randomization**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Not expected	7 (8.8)	7	0		0		7 (4.4)	7
AE related to study procedure								
Not related	52 (65.0)	111	19 (46.3)	30	22 (56.4)	47	93 (58.1)	188
Related	3 (3.8)	3	2 (4.9)	2	2 (5.1)	2	7 (4.4)	7
AE severity								
Mild	33 (41.3)	77	16 (39.0)	22	16 (41.0)	34	65 (40.6)	133
Moderate	23 (28.8)	29	8 (19.5)	8	10 (25.6)	13	41 (25.6)	50
Severe	8 (10.0)	8	2 (4.9)	2	2 (5.1)	2	12 (7.5)	12

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Post-Randomization**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Action taken due to AE								
Action taken with study product								
Product use interrupted	1 (1.3)	1	0		0		1 (0.6)	1
Product use stopped	0		0		0		0	
Product use reduced	0		0		0		0	
Not applicable	0		0		23 (59.0)	49	23 (14.4)	49
None	52 (65.0)	113	20 (48.8)	32	0		72 (45.0)	145
Treatment given								

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Post-Randomization**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Yes	13 (16.3)	14	8 (19.5)	8	6 (15.4)	8	27 (16.9)	30
No	46 (57.5)	100	17 (41.5)	24	21 (53.9)	41	84 (52.5)	165
Other action taken								
Prune Juice Given	2 (2.5)	2	0		0		2 (1.3)	2
Repeat Cbc In 1 Week Ordered	0		0		1 (2.6)	1	1 (0.6)	1
Repeated Lab	0		1 (2.4)	1	0		1 (0.6)	1
Subject Withdrew Consent	0		0		1 (2.6)	1	1 (0.6)	1
No action taken due to AE	45 (56.3)	97	16 (39.0)	23	0		61 (38.1)	120

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Confinement**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events (AE)	23 (28.8)	39	11 (26.8)	14	13 (33.3)	27	47 (29.4)	80
AE Serious								
Yes("SAE")	0		0		0		0	
No("AE")	23 (28.8)	39	11 (26.8)	14	13 (33.3)	27	47 (29.4)	80
AE related to IP								
Not related	23 (28.8)	34	10 (24.4)	13	13 (33.3)	27	46 (28.8)	74
Related	5 (6.3)	5	1 (2.4)	1	0		6 (3.8)	6
Expected	0		1 (2.4)	1	0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Confinement**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Not expected	5 (6.3)	5	0		0		5 (3.1)	5
AE related to study procedure								
Not related	22 (27.5)	37	10 (24.4)	12	12 (30.8)	25	44 (27.5)	74
Related	2 (2.5)	2	2 (4.9)	2	2 (5.1)	2	6 (3.8)	6
AE severity								
Mild	18 (22.5)	33	10 (24.4)	12	9 (23.1)	23	37 (23.1)	68
Moderate	6 (7.5)	6	2 (4.9)	2	4 (10.3)	4	12 (7.5)	12
Severe	0		0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Confinement**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Action taken due to AE								
Action taken with study product								
Product use interrupted	0		0		0		0	
Product use stopped	0		0		0		0	
Product use reduced	0		0		0		0	
Not applicable	0		0		13 (33.3)	27	13 (8.1)	27
None	23 (28.8)	39	11 (26.8)	14	0		34 (21.3)	53
Treatment given								

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Confinement**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Yes	2 (2.5)	2	1 (2.4)	1	1 (2.6)	1	4 (2.5)	4
No	21 (26.3)	37	10 (24.4)	13	12 (30.8)	26	43 (26.9)	76
Other action taken								
Prune Juice Given	2 (2.5)	2	0		0		2 (1.3)	2
Subject Withdrew Consent	0		0		1 (2.6)	1	1 (0.6)	1
No action taken due to AE	20 (25.0)	35	10 (24.4)	13	0		30 (18.8)	48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Ambulatory**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events (AE)	41 (51.3)	74	14 (34.2)	18	14 (35.9)	22	69 (43.1)	114
AE Serious								
Yes("SAE")	0		0		0		0	
No("AE")	41 (51.3)	74	14 (34.2)	18	14 (35.9)	22	69 (43.1)	114
AE related to IP								
Not related	41 (51.3)	72	14 (34.2)	18	14 (35.9)	22	69 (43.1)	112
Related	2 (2.5)	2	0		0		2 (1.3)	2
Expected	0		0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Ambulatory**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Not expected	2 (2.5)	2	0		0		2 (1.3)	2
AE related to study procedure								
Not related	41 (51.3)	73	14 (34.2)	18	14 (35.9)	22	69 (43.1)	113
Related	1 (1.3)	1	0		0		1 (0.6)	1
AE severity								
Mild	24 (30.0)	43	10 (24.4)	10	10 (25.6)	11	44 (27.5)	64
Moderate	18 (22.5)	23	6 (14.6)	6	7 (18.0)	9	31 (19.4)	38
Severe	8 (10.0)	8	2 (4.9)	2	2 (5.1)	2	12 (7.5)	12

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Ambulatory**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Action taken due to AE								
Action taken with study product								
Product use interrupted	1 (1.3)	1	0		0		1 (0.6)	1
Product use stopped	0		0		0		0	
Product use reduced	0		0		0		0	
Not applicable	0		0		14 (35.9)	22	14 (8.8)	22
None	41 (51.3)	73	14 (34.2)	18	0		55 (34.4)	91
Treatment given								

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Ambulatory**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Yes	11 (13.8)	12	7 (17.1)	7	5 (12.8)	7	23 (14.4)	26
No	33 (41.3)	62	8 (19.5)	11	10 (25.6)	15	51 (31.9)	88
Other action taken								
Repeat Cbc In 1 Week Ordered	0		0		1 (2.6)	1	1 (0.6)	1
Repeated Lab	0		1 (2.4)	1	0		1 (0.6)	1
No action taken due to AE	32 (40.0)	61	7 (17.1)	10	0		39 (24.4)	71

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Safety Follow-Up**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events (AE)	1 (1.3)	1	0		0		1 (0.6)	1
AE Serious								
Yes("SAE")	0		0		0		0	
No("AE")	1 (1.3)	1	0		0		1 (0.6)	1
AE related to IP								
Not related	1 (1.3)	1	0		0		1 (0.6)	1
Related	0		0		0		0	
Expected	0		0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Safety Follow-Up**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Not expected	0		0		0		0	
AE related to study procedure								
Not related	1 (1.3)	1	0		0		1 (0.6)	1
Related	0		0		0		0	
AE severity								
Mild	1 (1.3)	1	0		0		1 (0.6)	1
Moderate	0		0		0		0	
Severe	0		0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Safety Follow-Up**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Action taken due to AE								
Action taken with study product								
Product use interrupted	0		0		0		0	
Product use stopped	0		0		0		0	
Product use reduced	0		0		0		0	
Not applicable	0		0		0		0	
None	1 (1.3)	1	0		0		1 (0.6)	1
Treatment given								

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.1 Summary of Adverse Events - Safety Population****Safety Time Period: Safety Follow-Up**

Adverse Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Yes	0		0		0		0	
No	1 (1.3)	1	0		0		1 (0.6)	1
Other action taken								
No action taken due to AE	1 (1.3)	1	0		0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol, but were not enrolled.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product (THSm2.2 or mCC).

**Table 15.2.6.2 Summary of Adverse Events by Product Use Category in Ambulatory - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events (AE)	32 (47.8)	60	6 (60.0)	8	3 (100.0)	6
AE Serious						
Yes("SAE")	0		0		0	
No("AE")	32 (47.8)	60	6 (60.0)	8	3 (100.0)	6
AE related to IP						
Not related	32 (47.8)	58	6 (60.0)	8	3 (100.0)	6
Related	2 (3.0)	2	0		0	
Expected	0		0		0	
Not expected	2 (3.0)	2	0		0	
AE related to study procedure						
Not related	32 (47.8)	60	6 (60.0)	7	3 (100.0)	6

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol but were not enrolled

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product(THSm2.2 or mCC)

**Table 15.2.6.2 Summary of Adverse Events by Product Use Category in Ambulatory - Safety Population**

Within THS 2.2 (N=80)						
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n (%)	Events	n (%)	Events	n (%)	Events
Related	0		1 (10.0)	1	0	
AE severity						
Mild	19 (28.4)	34	3 (30.0)	5	2 (66.7)	4
Moderate	13 (19.4)	18	3 (30.0)	3	2 (66.7)	2
Severe	8 (11.9)	8	0		0	
Action taken due to AE						
Action taken with study product						
Product use interrupted	1 (1.5)	1	0		0	
Product use stopped	0		0		0	
Product use reduced	0		0		0	
Not applicable	0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol but were not enrolled

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product(THSm2.2 or mCC)

**Table 15.2.6.2 Summary of Adverse Events by Product Use Category in Ambulatory - Safety Population**

Within THS 2.2 (N=80)						
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n (%)	Events	n (%)	Events	n (%)	Events
None	32 (47.8)	59	6 (60.0)	8	3 (100.0)	6
Treatment given						
Yes	8 (11.9)	9	2 (20.0)	2	1 (33.3)	1
No	27 (40.3)	51	4 (40.0)	6	2 (66.7)	5
Other action taken						
No action taken due to AE	26 (38.8)	50	4 (40.0)	6	2 (66.7)	5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol but were not enrolled

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product(THSm2.2 or mCC)

**Table 15.2.6.2 Summary of Adverse Events by Product Use Category in Ambulatory - Safety Population**

	Within mCC (N=41)	
	CC (N=40)	
	n (%)	Events
Adverse events (AE)	14 (35.0)	18
AE Serious		
Yes("SAE")	0	
No("AE")	14 (35.0)	18
AE related to IP		
Not related	14 (35.0)	18
Related	0	
Expected	0	
Not expected	0	
AE related to study procedure		
Not related	14 (35.0)	18

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.but were not enrolled

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product(THSm2.2 or mCC)

**Table 15.2.6.2 Summary of Adverse Events by Product Use Category in Ambulatory - Safety Population**

	Within mCC (N=41)	
	CC (N=40)	
	n (%)	Events
Related	0	
AE severity		
Mild	10 (25.0)	10
Moderate	6 (15.0)	6
Severe	2 (5.0)	2
Action taken due to AE		
Action taken with study product		
Product use interrupted	0	
Product use stopped	0	
Product use reduced	0	
Not applicable	0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol but were not enrolled

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product(THSm2.2 or mCC)

**Table 15.2.6.2 Summary of Adverse Events by Product Use Category in Ambulatory - Safety Population**

	Within mCC (N=41)	
	CC (N=40)	
	n (%)	Events
None	14 (35.0)	18
Treatment given		
Yes	7 (17.5)	7
No	8 (20.0)	11
Other action taken		
Repeated Lab	1 (2.5)	1
No action taken due to AE	7 (17.5)	10

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol but were not enrolled

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product(THSm2.2 or mCC)

**Table 15.2.6.2 Summary of Adverse Events by Product Use Category in Ambulatory - Safety Population**

	Within SA (N=39)					
	Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
	n (%)	Events	n (%)	Events	n (%)	Events
Adverse events (AE)	1 (16.7)	2	2 (50.0)	4	11 (45.8)	16
AE Serious						
Yes("SAE")	0		0		0	
No("AE")	1 (16.7)	2	2 (50.0)	4	11 (45.8)	16
AE related to IP						
Not related	1 (16.7)	2	2 (50.0)	4	11 (45.8)	16
Related	0		0		0	
Expected	0		0		0	
Not expected	0		0		0	
AE related to study procedure						
Not related	1 (16.7)	2	2 (50.0)	4	11 (45.8)	16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.but were not enrolled

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product(THSm2.2 or mCC)

**Table 15.2.6.2 Summary of Adverse Events by Product Use Category in Ambulatory - Safety Population**

	Within SA (N=39)					
	Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
	n (%)	Events	n (%)	Events	n (%)	Events
Related	0		0		0	
AE severity						
Mild	0		1 (25.0)	1	9 (37.5)	10
Moderate	1 (16.7)	1	2 (50.0)	3	4 (16.7)	5
Severe	1 (16.7)	1	0		1 (4.2)	1
Action taken due to AE						
Action taken with study product						
Product use interrupted	0		0		0	
Product use stopped	0		0		0	
Product use reduced	0		0		0	
Not applicable	1 (16.7)	2	2 (50.0)	4	11 (45.8)	16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol but were not enrolled

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product(THSm2.2 or mCC)

**Table 15.2.6.2 Summary of Adverse Events by Product Use Category in Ambulatory - Safety Population**

	Within SA (N=39)					
	Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
	n (%)	Events	n (%)	Events	n (%)	Events
None	0		0		0	
Treatment given						
Yes	0		0		5 (20.8)	7
No	1 (16.7)	2	2 (50.0)	4	7 (29.2)	9
Other action taken						
Repeat Cbc In 1 Week Ordered	0		0		1 (4.2)	1
No action taken due to AE	0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol. but were not enrolled

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: IP=Investigational product(THSm2.2 or mCC)

Appendix 15.3.6.1

Study ID: ZRHM-REXA-08-US Program: t_ae_sum_produce.sas Status: Final

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**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	33 (41.3)	38	11 (26.8)	16	14 (35.9)	18	4 (80.0)	12	62 (37.6)	84
Eye disorders	1 (1.3)	1	0	0	0	0	0	0	1 (0.6)	1
Conjunctival hyperaemia	1 (1.3)	1							1 (0.6)	1
Gastrointestinal disorders	4 (5.0)	4	3 (7.3)	5	2 (5.1)	3	1 (20.0)	2	10 (6.1)	14
Abdominal pain	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1
Constipation	2 (2.5)	2	1 (2.4)	1	0	0	0	0	3 (1.8)	3
Dyspepsia	1 (1.3)	1	0	0	0	0	0	0	1 (0.6)	1
Flatulence	1 (1.3)	1	0	0	1 (2.6)	1	0	0	2 (1.2)	2
Nausea	0	0	2 (4.9)	2	1 (2.6)	1	1 (20.0)	1	4 (2.4)	4
Vomiting	0	0	1 (2.4)	1	1 (2.6)	1	1 (20.0)	1	3 (1.8)	3

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
General disorders and administration site conditions	1 (1.3)	2	1 (2.4)	1	0		0		2 (1.2)	3
Induration	1 (1.3)	1	0						1 (0.6)	1
Vessel puncture site bruise	1 (1.3)	1	0						1 (0.6)	1
Vessel puncture site haemorrhage	0		1 (2.4)	1					1 (0.6)	1
Infections and infestations	0		0		0		1 (20.0)	1	1 (0.6)	1
Sinusitis							1 (20.0)	1	1 (0.6)	1
Injury, poisoning and procedural complications	0		1 (2.4)	1	2 (5.1)	2	1 (20.0)	3	4 (2.4)	6
Administration related reaction			1 (2.4)	1	0		0		1 (0.6)	1
Excoriation			0		1 (2.6)	1	1 (20.0)	2	2 (1.2)	3
Procedural complication			0		0		1 (20.0)	1	1 (0.6)	1

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Procedural hypotension			0		1 (2.6)	1	0		1 (0.6)	1
Investigations	7 (8.8)	7	5 (12.2)	5	3 (7.7)	3	1 (20.0)	1	16 (9.7)	16
Blood creatinine increased	0		1 (2.4)	1	0		0		1 (0.6)	1
Blood pressure increased	0		0		0		1 (20.0)	1	1 (0.6)	1
Blood triglycerides increased	1 (1.3)	1	0		0		0		1 (0.6)	1
Haemoglobin decreased	1 (1.3)	1	0		0		0		1 (0.6)	1
Lymphocyte count increased	2 (2.5)	2	3 (7.3)	3	2 (5.1)	2	0		7 (4.2)	7
Carbon monoxide diffusing capacity decreased	2 (2.5)	2	1 (2.4)	1	1 (2.6)	1	0		4 (2.4)	4
Neutrophil count decreased	1 (1.3)	1	0		0		0		1 (0.6)	1
Metabolism and nutrition disorders	4 (5.0)	4	0		0		1 (20.0)	1	5 (3.0)	5

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Diabetic ketoacidosis	0						1 (20.0)	1	1 (0.6)	1
Hypercholesterolaemia	1 (1.3)	1					0		1 (0.6)	1
Hypertriglyceridaemia	3 (3.8)	3					0		3 (1.8)	3
Musculoskeletal and connective tissue disorders	2 (2.5)	2	0		1 (2.6)	1	0		3 (1.8)	3
Arthralgia	1 (1.3)	1			0				1 (0.6)	1
Back pain	0				1 (2.6)	1			1 (0.6)	1
Pain in extremity	1 (1.3)	1			0				1 (0.6)	1
Nervous system disorders	15 (18.8)	15	4 (9.8)	4	6 (15.4)	6	3 (60.0)	3	28 (17.0)	28
Dizziness	2 (2.5)	2	0		1 (2.6)	1	0		3 (1.8)	3
Headache	9 (11.3)	9	4 (9.8)	4	4 (10.3)	4	2 (40.0)	2	19 (11.5)	19

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Presyncope	1 (1.3)	1	0		1 (2.6)	1	0		2 (1.2)	2
Syncope	3 (3.8)	3	0		0		1 (20.0)	1	4 (2.4)	4
Psychiatric disorders	1 (1.3)	1	0		0		0		1 (0.6)	1
Anxiety	1 (1.3)	1							1 (0.6)	1
Respiratory, thoracic and mediastinal disorders	1 (1.3)	1	0		1 (2.6)	1	1 (20.0)	1	3 (1.8)	3
Cough	1 (1.3)	1			0		0		1 (0.6)	1
Epistaxis	0				0		1 (20.0)	1	1 (0.6)	1
Throat irritation	0				1 (2.6)	1	0		1 (0.6)	1
Skin and subcutaneous tissue disorders	1 (1.3)	1	0		1 (2.6)	2	0		2 (1.2)	3
Pruritus	0				1 (2.6)	1			1 (0.6)	1

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Skin irritation	1 (1.3)	1			0				1 (0.6)	1
Urticaria	0				1 (2.6)	1			1 (0.6)	1

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	52 (65.0)	114	20 (48.8)	32	23 (59.0)	49	95 (59.4)	195
Blood and lymphatic system disorders	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2
Anaemia	1 (1.3)	1			0		1 (0.6)	1
Leukocytosis	0				1 (2.6)	1	1 (0.6)	1
Ear and labyrinth disorders	0		0		1 (2.6)	1	1 (0.6)	1
Ear pain					1 (2.6)	1	1 (0.6)	1
Eye disorders	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3
Conjunctivitis	1 (1.3)	1			0		1 (0.6)	1
Eye pruritus	1 (1.3)	1			0		1 (0.6)	1
Scleral haemorrhage	0				1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Gastrointestinal disorders	15 (18.8)	20	2 (4.9)	2	3 (7.7)	3	20 (12.5)	25
Abdominal pain	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Constipation	3 (3.8)	3	0		0		3 (1.9)	3
Diarrhoea	1 (1.3)	1	0		0		1 (0.6)	1
Dry mouth	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3
Flatulence	1 (1.3)	1	0		0		1 (0.6)	1
Gingival bleeding	1 (1.3)	1	0		0		1 (0.6)	1
Gingival pain	1 (1.3)	1	0		0		1 (0.6)	1
Lip dry	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Nausea	3 (3.8)	3	0		1 (2.6)	1	4 (2.5)	4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Paraesthesia oral	1 (1.3)	1	0		0		1 (0.6)	1
Salivary hypersecretion	1 (1.3)	1	0		0		1 (0.6)	1
Toothache	2 (2.5)	3	0		1 (2.6)	1	3 (1.9)	4
Vomiting	1 (1.3)	1	0		0		1 (0.6)	1
General disorders and administration site conditions	2 (2.5)	2	0		2 (5.1)	2	4 (2.5)	4
Chest discomfort	1 (1.3)	1			0		1 (0.6)	1
Feeling hot	0				1 (2.6)	1	1 (0.6)	1
Non-cardiac chest pain	1 (1.3)	1			0		1 (0.6)	1
Pyrexia	0				1 (2.6)	1	1 (0.6)	1
Infections and infestations	5 (6.3)	5	5 (12.2)	5	1 (2.6)	1	11 (6.9)	11

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Oral herpes	0		1 (2.4)	1	0		1 (0.6)	1
Pharyngitis	1 (1.3)	1	0		0		1 (0.6)	1
Upper respiratory tract infection	3 (3.8)	3	4 (9.8)	4	1 (2.6)	1	8 (5.0)	8
Urinary tract infection	1 (1.3)	1	0		0		1 (0.6)	1
Injury, poisoning and procedural complications	5 (6.3)	6	4 (9.8)	4	3 (7.7)	3	12 (7.5)	13
Administration related reaction	0		2 (4.9)	2	0		2 (1.3)	2
Arthropod bite	0		0		1 (2.6)	1	1 (0.6)	1
Contusion	0		1 (2.4)	1	0		1 (0.6)	1
Excoriation	1 (1.3)	1	0		0		1 (0.6)	1
Laceration	1 (1.3)	1	0		0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Ligament sprain	3 (3.8)	3	0		0		3 (1.9)	3
Muscle strain	0		0		2 (5.1)	2	2 (1.3)	2
Thermal burn	1 (1.3)	1	0		0		1 (0.6)	1
Wound	0		1 (2.4)	1	0		1 (0.6)	1
Investigations	27 (33.8)	42	11 (26.8)	13	12 (30.8)	15	50 (31.3)	70
Alanine aminotransferase increased	1 (1.3)	1	0		0		1 (0.6)	1
Aspartate aminotransferase increased	1 (1.3)	2	1 (2.4)	1	0		2 (1.3)	3
Blood bilirubin increased	1 (1.3)	3	0		1 (2.6)	1	2 (1.3)	4
Blood cholesterol increased	0		0		1 (2.6)	1	1 (0.6)	1
Blood potassium increased	2 (2.5)	2	1 (2.4)	1	0		3 (1.9)	3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Blood triglycerides increased	2 (2.5)	2	2 (4.9)	3	2 (5.1)	2	6 (3.8)	7
Forced expiratory volume decreased	2 (2.5)	2	0		0		2 (1.3)	2
Gamma-glutamyltransferase increased	1 (1.3)	1	0		0		1 (0.6)	1
Haemoglobin decreased	11 (13.8)	14	4 (9.8)	5	6 (15.4)	8	21 (13.1)	27
Lymphocyte count increased	6 (7.5)	7	2 (4.9)	2	1 (2.6)	1	9 (5.6)	10
Neutrophil count decreased	4 (5.0)	5	0		0		4 (2.5)	5
Protein urine	0		0		1 (2.6)	1	1 (0.6)	1
Vital capacity decreased	2 (2.5)	2	0		0		2 (1.3)	2
Carbon monoxide diffusing capacity decreased	1 (1.3)	1	1 (2.4)	1	1 (2.6)	1	3 (1.9)	3
Metabolism and nutrition disorders	2 (2.5)	3	0		2 (5.1)	2	4 (2.5)	5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Hyperglycaemia	0				1 (2.6)	1	1 (0.6)	1
Hypertriglyceridaemia	2 (2.5)	3			0		2 (1.3)	3
Increased appetite	0				1 (2.6)	1	1 (0.6)	1
Musculoskeletal and connective tissue disorders	2 (2.5)	3	0		1 (2.6)	1	3 (1.9)	4
Back pain	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Muscle spasms	1 (1.3)	1			0		1 (0.6)	1
Pain in extremity	1 (1.3)	1			0		1 (0.6)	1
Nervous system disorders	7 (8.8)	7	1 (2.4)	1	4 (10.3)	6	12 (7.5)	14
Dizziness	1 (1.3)	1	0		2 (5.1)	2	3 (1.9)	3
Headache	4 (5.0)	4	1 (2.4)	1	3 (7.7)	4	8 (5.0)	9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Paraesthesia	1 (1.3)	1	0		0		1 (0.6)	1
Presyncope	1 (1.3)	1	0		0		1 (0.6)	1
Psychiatric disorders	1 (1.3)	1	1 (2.4)	1	3 (7.7)	5	5 (3.1)	7
Abnormal dreams	1 (1.3)	1	0		0		1 (0.6)	1
Anxiety	0		0		1 (2.6)	1	1 (0.6)	1
Depressed mood	0		0		1 (2.6)	1	1 (0.6)	1
Insomnia	0		0		1 (2.6)	1	1 (0.6)	1
Nightmare	0		1 (2.4)	1	0		1 (0.6)	1
Restlessness	0		0		1 (2.6)	1	1 (0.6)	1
Tension	0		0		1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Renal and urinary disorders	1 (1.3)	1	0		3 (7.7)	3	4 (2.5)	4
Dysuria	0				1 (2.6)	1	1 (0.6)	1
Proteinuria	0				1 (2.6)	1	1 (0.6)	1
Glycosuria	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Reproductive system and breast disorders	1 (1.3)	1	0		0		1 (0.6)	1
Erectile dysfunction	1 (1.3)	1					1 (0.6)	1
Respiratory, thoracic and mediastinal disorders	9 (11.3)	15	4 (9.8)	4	3 (7.7)	3	16 (10.0)	22
Cough	3 (3.8)	3	1 (2.4)	1	0		4 (2.5)	4
Dyspnoea	1 (1.3)	1	0		0		1 (0.6)	1
Nasal congestion	3 (3.8)	3	2 (4.9)	2	0		5 (3.1)	5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Nasal discomfort	0		0		1 (2.6)	1	1 (0.6)	1
Oropharyngeal pain	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3
Pulmonary congestion	1 (1.3)	1	0		0		1 (0.6)	1
Respiratory disorder	1 (1.3)	1	0		0		1 (0.6)	1
Rhinitis allergic	0		1 (2.4)	1	0		1 (0.6)	1
Rhinorrhoea	1 (1.3)	1	0		0		1 (0.6)	1
Sinus congestion	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2
Sneezing	1 (1.3)	1	0		0		1 (0.6)	1
Upper-airway cough syndrome	1 (1.3)	1	0		0		1 (0.6)	1
Skin and subcutaneous tissue disorders	3 (3.8)	5	1 (2.4)	2	2 (5.1)	2	6 (3.8)	9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Acne	2 (2.5)	2	0		0		2 (1.3)	2
Cold sweat	0		0		1 (2.6)	1	1 (0.6)	1
Erythema	0		0		1 (2.6)	1	1 (0.6)	1
Pruritus	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Rash	2 (2.5)	2	1 (2.4)	1	0		3 (1.9)	3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	23 (28.8)	39	11 (26.8)	14	13 (33.3)	27	47 (29.4)	80
Blood and lymphatic system disorders	1 (1.3)	1	0		0		1 (0.6)	1
Anaemia	1 (1.3)	1					1 (0.6)	1
Eye disorders	0		0		1 (2.6)	1	1 (0.6)	1
Scleral haemorrhage					1 (2.6)	1	1 (0.6)	1
Gastrointestinal disorders	9 (11.3)	10	2 (4.9)	2	3 (7.7)	3	14 (8.8)	15
Abdominal pain	0		1 (2.4)	1	0		1 (0.6)	1
Constipation	2 (2.5)	2	0		0		2 (1.3)	2
Dry mouth	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2
Flatulence	1 (1.3)	1	0		0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Lip dry	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Nausea	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3
Paraesthesia oral	1 (1.3)	1	0		0		1 (0.6)	1
Salivary hypersecretion	1 (1.3)	1	0		0		1 (0.6)	1
Toothache	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2
General disorders and administration site conditions	0		0		1 (2.6)	1	1 (0.6)	1
Feeling hot					1 (2.6)	1	1 (0.6)	1
Infections and infestations	1 (1.3)	1	2 (4.9)	2	0		3 (1.9)	3
Oral herpes	0		1 (2.4)	1			1 (0.6)	1
Pharyngitis	1 (1.3)	1	0				1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Upper respiratory tract infection	0		1 (2.4)	1			1 (0.6)	1
Injury, poisoning and procedural complications	0		3 (7.3)	3	1 (2.6)	1	4 (2.5)	4
Administration related reaction			2 (4.9)	2	0		2 (1.3)	2
Contusion			1 (2.4)	1	0		1 (0.6)	1
Muscle strain			0		1 (2.6)	1	1 (0.6)	1
Investigations	9 (11.3)	10	3 (7.3)	3	4 (10.3)	4	16 (10.0)	17
Blood potassium increased	0		1 (2.4)	1	0		1 (0.6)	1
Blood triglycerides increased	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2
Forced expiratory volume decreased	1 (1.3)	1	0		0		1 (0.6)	1
Haemoglobin decreased	3 (3.8)	3	0		2 (5.1)	2	5 (3.1)	5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Lymphocyte count increased	2 (2.5)	2	1 (2.4)	1	0		3 (1.9)	3
Neutrophil count decreased	1 (1.3)	1	0		0		1 (0.6)	1
Protein urine	0		0		1 (2.6)	1	1 (0.6)	1
Vital capacity decreased	1 (1.3)	1	0		0		1 (0.6)	1
Carbon monoxide diffusing capacity decreased	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Metabolism and nutrition disorders	0		0		1 (2.6)	1	1 (0.6)	1
Increased appetite					1 (2.6)	1	1 (0.6)	1
Musculoskeletal and connective tissue disorders	2 (2.5)	3	0		1 (2.6)	1	3 (1.9)	4
Back pain	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Muscle spasms	1 (1.3)	1			0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Pain in extremity	1 (1.3)	1			0		1 (0.6)	1
Nervous system disorders	6 (7.5)	6	0		3 (7.7)	5	9 (5.6)	11
Dizziness	1 (1.3)	1			2 (5.1)	2	3 (1.9)	3
Headache	3 (3.8)	3			2 (5.1)	3	5 (3.1)	6
Paraesthesia	1 (1.3)	1			0		1 (0.6)	1
Presyncope	1 (1.3)	1			0		1 (0.6)	1
Psychiatric disorders	1 (1.3)	1	1 (2.4)	1	3 (7.7)	5	5 (3.1)	7
Abnormal dreams	1 (1.3)	1	0		0		1 (0.6)	1
Anxiety	0		0		1 (2.6)	1	1 (0.6)	1
Depressed mood	0		0		1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Insomnia	0		0		1 (2.6)	1	1 (0.6)	1
Nightmare	0		1 (2.4)	1	0		1 (0.6)	1
Restlessness	0		0		1 (2.6)	1	1 (0.6)	1
Tension	0		0		1 (2.6)	1	1 (0.6)	1
Respiratory, thoracic and mediastinal disorders	4 (5.0)	6	1 (2.4)	1	3 (7.7)	3	8 (5.0)	10
Cough	1 (1.3)	1	0		0		1 (0.6)	1
Dyspnoea	1 (1.3)	1	0		0		1 (0.6)	1
Nasal congestion	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Nasal discomfort	0		0		1 (2.6)	1	1 (0.6)	1
Oropharyngeal pain	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Sinus congestion	0		0		1 (2.6)	1	1 (0.6)	1
Sneezing	1 (1.3)	1	0		0		1 (0.6)	1
Upper-airway cough syndrome	1 (1.3)	1	0		0		1 (0.6)	1
Skin and subcutaneous tissue disorders	1 (1.3)	1	1 (2.4)	2	2 (5.1)	2	4 (2.5)	5
Acne	1 (1.3)	1	0		0		1 (0.6)	1
Cold sweat	0		0		1 (2.6)	1	1 (0.6)	1
Erythema	0		0		1 (2.6)	1	1 (0.6)	1
Pruritus	0		1 (2.4)	1	0		1 (0.6)	1
Rash	0		1 (2.4)	1	0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	41 (51.3)	74	14 (34.2)	18	14 (35.9)	22	69 (43.1)	114
Blood and lymphatic system disorders	0		0		1 (2.6)	1	1 (0.6)	1
Leukocytosis					1 (2.6)	1	1 (0.6)	1
Ear and labyrinth disorders	0		0		1 (2.6)	1	1 (0.6)	1
Ear pain					1 (2.6)	1	1 (0.6)	1
Eye disorders	2 (2.5)	2	0		0		2 (1.3)	2
Conjunctivitis	1 (1.3)	1					1 (0.6)	1
Eye pruritus	1 (1.3)	1					1 (0.6)	1
Gastrointestinal disorders	7 (8.8)	10	0		0		7 (4.4)	10
Abdominal pain	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Constipation	1 (1.3)	1					1 (0.6)	1
Diarrhoea	1 (1.3)	1					1 (0.6)	1
Dry mouth	1 (1.3)	1					1 (0.6)	1
Gingival bleeding	1 (1.3)	1					1 (0.6)	1
Gingival pain	1 (1.3)	1					1 (0.6)	1
Nausea	1 (1.3)	1					1 (0.6)	1
Toothache	1 (1.3)	2					1 (0.6)	2
Vomiting	1 (1.3)	1					1 (0.6)	1
General disorders and administration site conditions	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3
Chest discomfort	1 (1.3)	1			0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Non-cardiac chest pain	1 (1.3)	1			0		1 (0.6)	1
Pyrexia	0				1 (2.6)	1	1 (0.6)	1
Infections and infestations	4 (5.0)	4	3 (7.3)	3	1 (2.6)	1	8 (5.0)	8
Upper respiratory tract infection	3 (3.8)	3	3 (7.3)	3	1 (2.6)	1	7 (4.4)	7
Urinary tract infection	1 (1.3)	1	0		0		1 (0.6)	1
Injury, poisoning and procedural complications	5 (6.3)	6	1 (2.4)	1	2 (5.1)	2	8 (5.0)	9
Arthropod bite	0		0		1 (2.6)	1	1 (0.6)	1
Excoriation	1 (1.3)	1	0		0		1 (0.6)	1
Laceration	1 (1.3)	1	0		0		1 (0.6)	1
Ligament sprain	3 (3.8)	3	0		0		3 (1.9)	3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Muscle strain	0		0		1 (2.6)	1	1 (0.6)	1
Thermal burn	1 (1.3)	1	0		0		1 (0.6)	1
Wound	0		1 (2.4)	1	0		1 (0.6)	1
Investigations	20 (25.0)	31	8 (19.5)	10	9 (23.1)	11	37 (23.1)	52
Alanine aminotransferase increased	1 (1.3)	1	0		0		1 (0.6)	1
Aspartate aminotransferase increased	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Blood bilirubin increased	1 (1.3)	3	0		1 (2.6)	1	2 (1.3)	4
Blood cholesterol increased	0		0		1 (2.6)	1	1 (0.6)	1
Blood potassium increased	2 (2.5)	2	0		0		2 (1.3)	2
Blood triglycerides increased	1 (1.3)	1	2 (4.9)	3	1 (2.6)	1	4 (2.5)	5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Forced expiratory volume decreased	1 (1.3)	1	0		0		1 (0.6)	1
Gamma-glutamyltransferase increased	1 (1.3)	1	0		0		1 (0.6)	1
Haemoglobin decreased	8 (10.0)	11	4 (9.8)	5	5 (12.8)	6	17 (10.6)	22
Lymphocyte count increased	5 (6.3)	5	1 (2.4)	1	1 (2.6)	1	7 (4.4)	7
Neutrophil count decreased	3 (3.8)	4	0		0		3 (1.9)	4
Vital capacity decreased	1 (1.3)	1	0		0		1 (0.6)	1
Carbon monoxide diffusing capacity decreased	0		0		1 (2.6)	1	1 (0.6)	1
Metabolism and nutrition disorders	2 (2.5)	3	0		1 (2.6)	1	3 (1.9)	4
Hyperglycaemia	0				1 (2.6)	1	1 (0.6)	1
Hypertriglyceridaemia	2 (2.5)	3			0		2 (1.3)	3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Nervous system disorders	1 (1.3)	1	1 (2.4)	1	1 (2.6)	1	3 (1.9)	3
Headache	1 (1.3)	1	1 (2.4)	1	1 (2.6)	1	3 (1.9)	3
Renal and urinary disorders	1 (1.3)	1	0		3 (7.7)	3	4 (2.5)	4
Dysuria	0				1 (2.6)	1	1 (0.6)	1
Proteinuria	0				1 (2.6)	1	1 (0.6)	1
Glycosuria	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Reproductive system and breast disorders	1 (1.3)	1	0		0		1 (0.6)	1
Erectile dysfunction	1 (1.3)	1					1 (0.6)	1
Respiratory, thoracic and mediastinal disorders	5 (6.3)	9	3 (7.3)	3	0		8 (5.0)	12
Cough	2 (2.5)	2	1 (2.4)	1			3 (1.9)	3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Nasal congestion	2 (2.5)	2	1 (2.4)	1			3 (1.9)	3
Oropharyngeal pain	1 (1.3)	1	0				1 (0.6)	1
Pulmonary congestion	1 (1.3)	1	0				1 (0.6)	1
Respiratory disorder	1 (1.3)	1	0				1 (0.6)	1
Rhinitis allergic	0		1 (2.4)	1			1 (0.6)	1
Rhinorrhoea	1 (1.3)	1	0				1 (0.6)	1
Sinus congestion	1 (1.3)	1	0				1 (0.6)	1
Skin and subcutaneous tissue disorders	2 (2.5)	4	0		0		2 (1.3)	4
Acne	1 (1.3)	1					1 (0.6)	1
Pruritus	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Rash	2 (2.5)	2					2 (1.3)	2

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.3 Summary of Adverse Events by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Safety Follow-Up**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	1 (1.3)	1	0		0		1 (0.6)	1
Investigations	1 (1.3)	1	0		0		1 (0.6)	1
Aspartate aminotransferase increased	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3.1 Summary of Adverse Events (incidence >5% in any Study Arm) by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	33 (41.3)	38	11 (26.8)	16	14 (35.9)	18	4 (80.0)	12	62 (37.6)	84
Gastrointestinal disorders	4 (5.0)	4	3 (7.3)	5	2 (5.1)	3	1 (20.0)	2	10 (6.1)	14
Nausea	0		2 (4.9)	2	1 (2.6)	1	1 (20.0)	1	4 (2.4)	4
Vomiting	0		1 (2.4)	1	1 (2.6)	1	1 (20.0)	1	3 (1.8)	3
Infections and infestations	0		0		0		1 (20.0)	1	1 (0.6)	1
Sinusitis							1 (20.0)	1	1 (0.6)	1
Injury, poisoning and procedural complications	0		1 (2.4)	1	2 (5.1)	2	1 (20.0)	3	4 (2.4)	6
Excoriation			0		1 (2.6)	1	1 (20.0)	2	2 (1.2)	3

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3.1 Summary of Adverse Events (incidence >5% in any Study Arm) by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Procedural complication			0		0		1 (20.0)	1	1 (0.6)	1
Investigations	7 (8.8)	7	5 (12.2)	5	3 (7.7)	3	1 (20.0)	1	16 (9.7)	16
Blood pressure increased	0		0		0		1 (20.0)	1	1 (0.6)	1
Lymphocyte count increased	2 (2.5)	2	3 (7.3)	3	2 (5.1)	2	0		7 (4.2)	7
Metabolism and nutrition disorders	4 (5.0)	4	0		0		1 (20.0)	1	5 (3.0)	5
Diabetic ketoacidosis	0						1 (20.0)	1	1 (0.6)	1
Nervous system disorders	15 (18.8)	15	4 (9.8)	4	6 (15.4)	6	3 (60.0)	3	28 (17.0)	28
Headache	9 (11.3)	9	4 (9.8)	4	4 (10.3)	4	2 (40.0)	2	19 (11.5)	19

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3.1 Summary of Adverse Events (incidence >5% in any Study Arm) by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Syncope	3 (3.8)	3	0		0		1 (20.0)	1	4 (2.4)	4
Respiratory, thoracic and mediastinal disorders	1 (1.3)	1	0		1 (2.6)	1	1 (20.0)	1	3 (1.8)	3
Epistaxis	0				0		1 (20.0)	1	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3.1 Summary of Adverse Events (incidence >5% in any Study Arm) by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	52 (65.0)	114	20 (48.8)	32	23 (59.0)	49	95 (59.4)	195
Gastrointestinal disorders	15 (18.8)	20	2 (4.9)	2	3 (7.7)	3	20 (12.5)	25
General disorders and administration site conditions	2 (2.5)	2	0		2 (5.1)	2	4 (2.5)	4
Infections and infestations	5 (6.3)	5	5 (12.2)	5	1 (2.6)	1	11 (6.9)	11
Upper respiratory tract infection	3 (3.8)	3	4 (9.8)	4	1 (2.6)	1	8 (5.0)	8
Injury, poisoning and procedural complications	5 (6.3)	6	4 (9.8)	4	3 (7.7)	3	12 (7.5)	13
Muscle strain	0		0		2 (5.1)	2	2 (1.3)	2
Investigations	27 (33.8)	42	11 (26.8)	13	12 (30.8)	15	50 (31.3)	70

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3.1 Summary of Adverse Events (incidence >5% in any Study Arm) by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Blood triglycerides increased	2 (2.5)	2	2 (4.9)	3	2 (5.1)	2	6 (3.8)	7
Haemoglobin decreased	11 (13.8)	14	4 (9.8)	5	6 (15.4)	8	21 (13.1)	27
Lymphocyte count increased	6 (7.5)	7	2 (4.9)	2	1 (2.6)	1	9 (5.6)	10
Metabolism and nutrition disorders	2 (2.5)	3	0		2 (5.1)	2	4 (2.5)	5
Nervous system disorders	7 (8.8)	7	1 (2.4)	1	4 (10.3)	6	12 (7.5)	14
Dizziness	1 (1.3)	1	0		2 (5.1)	2	3 (1.9)	3
Headache	4 (5.0)	4	1 (2.4)	1	3 (7.7)	4	8 (5.0)	9
Psychiatric disorders	1 (1.3)	1	1 (2.4)	1	3 (7.7)	5	5 (3.1)	7

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3.1 Summary of Adverse Events (incidence >5% in any Study Arm) by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Renal and urinary disorders	1 (1.3)	1	0		3 (7.7)	3	4 (2.5)	4
Respiratory, thoracic and mediastinal disorders	9 (11.3)	15	4 (9.8)	4	3 (7.7)	3	16 (10.0)	22
Skin and subcutaneous tissue disorders	3 (3.8)	5	1 (2.4)	2	2 (5.1)	2	6 (3.8)	9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.3.1 Summary of Adverse Events (incidence >5% in any Study Arm) by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	23 (28.8)	39	11 (26.8)	14	13 (33.3)	27	47 (29.4)	80
Gastrointestinal disorders	9 (11.3)	10	2 (4.9)	2	3 (7.7)	3	14 (8.8)	15
Injury, poisoning and procedural complications	0		3 (7.3)	3	1 (2.6)	1	4 (2.5)	4
Investigations	9 (11.3)	10	3 (7.3)	3	4 (10.3)	4	16 (10.0)	17
Haemoglobin decreased	3 (3.8)	3	0		2 (5.1)	2	5 (3.1)	5
Nervous system disorders	6 (7.5)	6	0		3 (7.7)	5	9 (5.6)	11
Dizziness	1 (1.3)	1			2 (5.1)	2	3 (1.9)	3
Headache	3 (3.8)	3			2 (5.1)	3	5 (3.1)	6

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3.1 Summary of Adverse Events (incidence >5% in any Study Arm) by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Psychiatric disorders	1 (1.3)	1	1 (2.4)	1	3 (7.7)	5	5 (3.1)	7
Respiratory, thoracic and mediastinal disorders	4 (5.0)	6	1 (2.4)	1	3 (7.7)	3	8 (5.0)	10
Skin and subcutaneous tissue disorders	1 (1.3)	1	1 (2.4)	2	2 (5.1)	2	4 (2.5)	5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3.1 Summary of Adverse Events (incidence >5% in any Study Arm) by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	41 (51.3)	74	14 (34.2)	18	14 (35.9)	22	69 (43.1)	114
Gastrointestinal disorders	7 (8.8)	10	0		0		7 (4.4)	10
Infections and infestations	4 (5.0)	4	3 (7.3)	3	1 (2.6)	1	8 (5.0)	8
Upper respiratory tract infection	3 (3.8)	3	3 (7.3)	3	1 (2.6)	1	7 (4.4)	7
Injury, poisoning and procedural complications	5 (6.3)	6	1 (2.4)	1	2 (5.1)	2	8 (5.0)	9
Investigations	20 (25.0)	31	8 (19.5)	10	9 (23.1)	11	37 (23.1)	52
Haemoglobin decreased	8 (10.0)	11	4 (9.8)	5	5 (12.8)	6	17 (10.6)	22
Lymphocyte count increased	5 (6.3)	5	1 (2.4)	1	1 (2.6)	1	7 (4.4)	7

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.3.1 Summary of Adverse Events (incidence >5% in any Study Arm) by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Renal and urinary disorders	1 (1.3)	1	0		3 (7.7)	3	4 (2.5)	4
Respiratory, thoracic and mediastinal disorders	5 (6.3)	9	3 (7.3)	3	0		8 (5.0)	12

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.3.1 Summary of Adverse Events (incidence >5% in any Study Arm) by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Safety Follow-Up**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events

No Adverse events with Incidence>5% in any Study Arm were reported in safety Follow-Up period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol
Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.4 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

Within THS 2.2 (N=80)						
System Organ Class Preferred Term	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	32 (47.8)	60	6 (60.0)	8	3 (100.0)	6
Eye disorders	2 (3.0)	2	0		0	
Conjunctivitis	1 (1.5)	1				
Eye pruritus	1 (1.5)	1				
Gastrointestinal disorders	5 (7.5)	8	2 (20.0)	2	0	
Abdominal pain	1 (1.5)	1	0			
Constipation	0		1 (10.0)	1		
Diarrhoea	1 (1.5)	1	0			
Dry mouth	1 (1.5)	1	0			

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.4 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

Within THS 2.2 (N=80)						
System Organ Class Preferred Term	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Gingival bleeding	1 (1.5)	1	0			
Gingival pain	1 (1.5)	1	0			
Nausea	0		1 (10.0)	1		
Toothache	1 (1.5)	2	0			
Vomiting	1 (1.5)	1	0			
General disorders and administration site conditions	2 (3.0)	2	0		0	
Chest discomfort	1 (1.5)	1				
Non-cardiac chest pain	1 (1.5)	1				
Infections and infestations	4 (6.0)	4	0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.4 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

Within THS 2.2 (N=80)						
System Organ Class Preferred Term	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Upper respiratory tract infection	3 (4.5)	3				
Urinary tract infection	1 (1.5)	1				
Injury, poisoning and procedural complications	2 (3.0)	2	1 (10.0)	1	2 (66.7)	3
Excoriation	0		0		1 (33.3)	1
Laceration	1 (1.5)	1	0		0	
Ligament sprain	0		1 (10.0)	1	2 (66.7)	2
Thermal burn	1 (1.5)	1	0		0	
Investigations	16 (23.9)	24	3 (30.0)	4	1 (33.3)	3
Alanine aminotransferase increased	1 (1.5)	1	0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.4 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

Within THS 2.2 (N=80)						
System Organ Class Preferred Term	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Aspartate aminotransferase increased	1 (1.5)	1	0		0	
Blood bilirubin increased	1 (1.5)	3	0		0	
Blood potassium increased	2 (3.0)	2	0		0	
Blood triglycerides increased	0		1 (10.0)	1	0	
Forced expiratory volume decreased	0		0		1 (33.3)	1
Gamma-glutamyltransferase increased	1 (1.5)	1	0		0	
Haemoglobin decreased	7 (10.5)	10	1 (10.0)	1	0	
Lymphocyte count increased	4 (6.0)	4	0		1 (33.3)	1
Neutrophil count decreased	2 (3.0)	2	1 (10.0)	2	0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.4 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

Within THS 2.2 (N=80)						
System Organ Class Preferred Term	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Vital capacity decreased	0		0		1 (33.3)	1
Metabolism and nutrition disorders	2 (3.0)	3	0		0	
Hypertriglyceridaemia	2 (3.0)	3				
Nervous system disorders	1 (1.5)	1	0		0	
Headache	1 (1.5)	1				
Renal and urinary disorders	1 (1.5)	1	0		0	
Glycosuria	1 (1.5)	1				
Reproductive system and breast disorders	1 (1.5)	1	0		0	
Erectile dysfunction	1 (1.5)	1				

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.4 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

Within THS 2.2 (N=80)						
System Organ Class Preferred Term	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Respiratory, thoracic and mediastinal disorders	5 (7.5)	9	0		0	
Cough	2 (3.0)	2				
Nasal congestion	2 (3.0)	2				
Oropharyngeal pain	1 (1.5)	1				
Pulmonary congestion	1 (1.5)	1				
Respiratory disorder	1 (1.5)	1				
Rhinorrhoea	1 (1.5)	1				
Sinus congestion	1 (1.5)	1				
Skin and subcutaneous tissue disorders	1 (1.5)	3	1 (10.0)	1	0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

Appendix 15.3.6.1

Study ID: ZRHM-REXA-08-US Program: t_ae_soc_sum_produce.sas Status: Final

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**Table 15.2.6.4 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

Within THS 2.2 (N=80)						
System Organ Class Preferred Term	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Acne	1 (1.5)	1	0			
Pruritus	1 (1.5)	1	0			
Rash	1 (1.5)	1	1 (10.0)	1		

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.4 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

System Organ Class Preferred Term	Within mCC (N=41)	
	CC (N=40)	
	n(%)	Events
Any adverse events	14 (35.0)	18
Infections and infestations	3 (7.5)	3
Upper respiratory tract infection	3 (7.5)	3
Injury, poisoning and procedural complications	1 (2.5)	1
Wound	1 (2.5)	1
Investigations	8 (20.0)	10
Aspartate aminotransferase increased	1 (2.5)	1
Blood triglycerides increased	2 (5.0)	3
Haemoglobin decreased	4 (10.0)	5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.4 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

Within mCC (N=41)		CC (N=40)	
System Organ Class Preferred Term			
		n(%)	Events
Lymphocyte count increased		1 (2.5)	1
Nervous system disorders		1 (2.5)	1
Headache		1 (2.5)	1
Respiratory, thoracic and mediastinal disorders		3 (7.5)	3
Cough		1 (2.5)	1
Nasal congestion		1 (2.5)	1
Rhinitis allergic		1 (2.5)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.4 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

System Organ Class Preferred Term	Within SA (N=39)					
	Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	1 (16.7)	2	2 (50.0)	4	11 (45.8)	16
Blood and lymphatic system disorders	0		0		1 (4.2)	1
Leukocytosis					1 (4.2)	1
Ear and labyrinth disorders	0		0		1 (4.2)	1
Ear pain					1 (4.2)	1
General disorders and administration site conditions	0		0		1 (4.2)	1
Pyrexia					1 (4.2)	1
Infections and infestations	0		0		1 (4.2)	1
Upper respiratory tract infection					1 (4.2)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.4 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

System Organ Class Preferred Term	Within SA (N=39)					
	Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
	n(%)	Events	n(%)	Events	n(%)	Events
Injury, poisoning and procedural complications	0		0		2 (8.3)	2
Arthropod bite					1 (4.2)	1
Muscle strain					1 (4.2)	1
Investigations	1 (16.7)	2	2 (50.0)	2	6 (25.0)	7
Blood bilirubin increased	0		0		1 (4.2)	1
Blood cholesterol increased	0		0		1 (4.2)	1
Blood triglycerides increased	0		0		1 (4.2)	1
Haemoglobin decreased	1 (16.7)	2	1 (25.0)	1	3 (12.5)	3
Lymphocyte count increased	0		1 (25.0)	1	0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.4 Summary of Adverse Events by Product Use Category, System Organ Class and Preferred Term - Safety Population**

System Organ Class Preferred Term	Within SA (N=39)					
	Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
	n(%)	Events	n(%)	Events	n(%)	Events
Carbon monoxide diffusing capacity decreased	0		0		1 (4.2)	1
Metabolism and nutrition disorders	0		0		1 (4.2)	1
Hyperglycaemia					1 (4.2)	1
Nervous system disorders	0		0		1 (4.2)	1
Headache					1 (4.2)	1
Renal and urinary disorders	0		2 (50.0)	2	1 (4.2)	1
Dysuria			1 (25.0)	1	0	
Proteinuria			1 (25.0)	1	0	
Glycosuria			0		1 (4.2)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	33 (41.3)	38	11 (26.8)	16	14 (35.9)	18	4 (80.0)	12	62 (37.6)	84
Related to IP	1 (1.3)	1	0		0		0		1 (0.6)	1
Expected	1 (1.3)	1	0		0		0		1 (0.6)	1
Not expected	0		0		0		0		0	
Eye disorders	1 (1.3)	1	0		0		0		1 (0.6)	1
Conjunctival hyperaemia	1 (1.3)	1							1 (0.6)	1
Related to IP	0								0	
Gastrointestinal disorders	4 (5.0)	4	3 (7.3)	5	2 (5.1)	3	1 (20.0)	2	10 (6.1)	14
Abdominal pain	0		1 (2.4)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0		0	

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Constipation	2 (2.5)	2	1 (2.4)	1	0		0		3 (1.8)	3
Related to IP	0		0		0		0		0	
Dyspepsia	1 (1.3)	1	0		0		0		1 (0.6)	1
Related to IP	0		0		0		0		0	
Flatulence	1 (1.3)	1	0		1 (2.6)	1	0		2 (1.2)	2
Related to IP	0		0		0		0		0	
Nausea	0		2 (4.9)	2	1 (2.6)	1	1 (20.0)	1	4 (2.4)	4
Related to IP	0		0		0		0		0	
Vomiting	0		1 (2.4)	1	1 (2.6)	1	1 (20.0)	1	3 (1.8)	3
Related to IP	0		0		0		0		0	

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
General disorders and administration site conditions	1 (1.3)	2	1 (2.4)	1	0		0		2 (1.2)	3
Induration	1 (1.3)	1	0						1 (0.6)	1
Related to IP	0		0						0	
Vessel puncture site bruise	1 (1.3)	1	0						1 (0.6)	1
Related to IP	0		0						0	
Vessel puncture site haemorrhage	0		1 (2.4)	1					1 (0.6)	1
Related to IP	0		0						0	
Infections and infestations	0		0		0		1 (20.0)	1	1 (0.6)	1
Sinusitis							1 (20.0)	1	1 (0.6)	1
Related to IP							0		0	

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Injury, poisoning and procedural complications	0		1 (2.4)	1	2 (5.1)	2	1 (20.0)	3	4 (2.4)	6
Administration related reaction			1 (2.4)	1	0		0		1 (0.6)	1
Related to IP			0		0		0		0	
Excoriation			0		1 (2.6)	1	1 (20.0)	2	2 (1.2)	3
Related to IP			0		0		0		0	
Procedural complication			0		0		1 (20.0)	1	1 (0.6)	1
Related to IP			0		0		0		0	
Procedural hypotension			0		1 (2.6)	1	0		1 (0.6)	1
Related to IP			0		0		0		0	
Investigations	7 (8.8)	7	5 (12.2)	5	3 (7.7)	3	1 (20.0)	1	16 (9.7)	16

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product (THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Blood creatinine increased	0		1 (2.4)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0		0	
Blood pressure increased	0		0		0		1 (20.0)	1	1 (0.6)	1
Related to IP	0		0		0		0		0	
Blood triglycerides increased	1 (1.3)	1	0		0		0		1 (0.6)	1
Related to IP	0		0		0		0		0	
Carbon monoxide diffusing capacity decreased	2 (2.5)	2	1 (2.4)	1	1 (2.6)	1	0		4 (2.4)	4
Related to IP	0		0		0		0		0	
Haemoglobin decreased	1 (1.3)	1	0		0		0		1 (0.6)	1
Related to IP	0		0		0		0		0	

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Lymphocyte count increased	2 (2.5)	2	3 (7.3)	3	2 (5.1)	2	0		7 (4.2)	7
Related to IP	0		0		0		0		0	
Neutrophil count decreased	1 (1.3)	1	0		0		0		1 (0.6)	1
Related to IP	0		0		0		0		0	
Metabolism and nutrition disorders	4 (5.0)	4	0		0		1 (20.0)	1	5 (3.0)	5
Diabetic ketoacidosis	0						1 (20.0)	1	1 (0.6)	1
Related to IP	0						0		0	
Hypercholesterolaemia	1 (1.3)	1					0		1 (0.6)	1
Related to IP	0						0		0	
Hypertriglyceridaemia	3 (3.8)	3					0		3 (1.8)	3

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0						0		0	
Musculoskeletal and connective tissue disorders	2 (2.5)	2	0		1 (2.6)	1	0		3 (1.8)	3
Arthralgia	1 (1.3)	1			0				1 (0.6)	1
Related to IP	0				0				0	
Back pain	0				1 (2.6)	1			1 (0.6)	1
Related to IP	0				0				0	
Pain in extremity	1 (1.3)	1			0				1 (0.6)	1
Related to IP	0				0				0	
Nervous system disorders	15 (18.8)	15	4 (9.8)	4	6 (15.4)	6	3 (60.0)	3	28 (17.0)	28
Dizziness	2 (2.5)	2	0		1 (2.6)	1	0		3 (1.8)	3

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product (THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	1 (1.3)	1	0		0		0		1 (0.6)	1
Expected	1 (1.3)	1	0		0		0		1 (0.6)	1
Headache	9 (11.3)	9	4 (9.8)	4	4 (10.3)	4	2 (40.0)	2	19 (11.5)	19
Related to IP	0		0		0		0		0	
Presyncope	1 (1.3)	1	0		1 (2.6)	1	0		2 (1.2)	2
Related to IP	0		0		0		0		0	
Syncope	3 (3.8)	3	0		0		1 (20.0)	1	4 (2.4)	4
Related to IP	0		0		0		0		0	
Psychiatric disorders	1 (1.3)	1	0		0		0		1 (0.6)	1
Anxiety	1 (1.3)	1							1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0								0	
Respiratory, thoracic and mediastinal disorders	1 (1.3)	1	0		1 (2.6)	1	1 (20.0)	1	3 (1.8)	3
Cough	1 (1.3)	1			0		0		1 (0.6)	1
Related to IP	0				0		0		0	
Epistaxis	0				0		1 (20.0)	1	1 (0.6)	1
Related to IP	0				0		0		0	
Throat irritation	0				1 (2.6)	1	0		1 (0.6)	1
Related to IP	0				0		0		0	
Skin and subcutaneous tissue disorders	1 (1.3)	1	0		1 (2.6)	2	0		2 (1.2)	3
Pruritus	0				1 (2.6)	1			1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product (THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0				0				0	
Skin irritation	1 (1.3)	1			0				1 (0.6)	1
Related to IP	0				0				0	
Urticaria	0				1 (2.6)	1			1 (0.6)	1
Related to IP	0				0				0	

Note: "Product Test" refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	52 (65.0)	114	20 (48.8)	32	23 (59.0)	49	95 (59.4)	195
Related to IP	7 (8.8)	7	1 (2.4)	1	0		8 (5.0)	8
Expected	0		1 (2.4)	1	0		1 (0.6)	1
Not expected	7 (8.8)	7	0		0		7 (4.4)	7
Blood and lymphatic system disorders	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2
Anaemia	1 (1.3)	1			0		1 (0.6)	1
Related to IP	0				0		0	
Leukocytosis	0				1 (2.6)	1	1 (0.6)	1
Related to IP	0				0		0	
Ear and labyrinth disorders	0		0		1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Ear pain					1 (2.6)	1	1 (0.6)	1
Related to IP					0		0	
Eye disorders	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3
Conjunctivitis	1 (1.3)	1			0		1 (0.6)	1
Related to IP	0				0		0	
Eye pruritus	1 (1.3)	1			0		1 (0.6)	1
Related to IP	0				0		0	
Scleral haemorrhage	0				1 (2.6)	1	1 (0.6)	1
Related to IP	0				0		0	
Gastrointestinal disorders	15 (18.8)	20	2 (4.9)	2	3 (7.7)	3	20 (12.5)	25

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Abdominal pain	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Related to IP	0		0		0		0	
Constipation	3 (3.8)	3	0		0		3 (1.9)	3
Related to IP	0		0		0		0	
Diarrhoea	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Dry mouth	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3
Related to IP	1 (1.3)	1	0		0		1 (0.6)	1
Not expected	1 (1.3)	1	0		0		1 (0.6)	1
Flatulence	1 (1.3)	1	0		0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0		0	
Gingival bleeding	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Gingival pain	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Lip dry	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Related to IP	0		0		0		0	
Nausea	3 (3.8)	3	0		1 (2.6)	1	4 (2.5)	4
Related to IP	0		0		0		0	
Paraesthesia oral	1 (1.3)	1	0		0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0		0	
Salivary hypersecretion	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	1 (1.3)	1	0		0		1 (0.6)	1
Not expected	1 (1.3)	1	0		0		1 (0.6)	1
Toothache	2 (2.5)	3	0		1 (2.6)	1	3 (1.9)	4
Related to IP	0		0		0		0	
Vomiting	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
General disorders and administration site conditions	2 (2.5)	2	0		2 (5.1)	2	4 (2.5)	4
Chest discomfort	1 (1.3)	1			0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0				0		0	
Feeling hot	0				1 (2.6)	1	1 (0.6)	1
Related to IP	0				0		0	
Non-cardiac chest pain	1 (1.3)	1			0		1 (0.6)	1
Related to IP	1 (1.3)	1			0		1 (0.6)	1
Not expected	1 (1.3)	1			0		1 (0.6)	1
Pyrexia	0				1 (2.6)	1	1 (0.6)	1
Related to IP	0				0		0	
Infections and infestations	5 (6.3)	5	5 (12.2)	5	1 (2.6)	1	11 (6.9)	11
Oral herpes	0		1 (2.4)	1	0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product (THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0		0	
Pharyngitis	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Upper respiratory tract infection	3 (3.8)	3	4 (9.8)	4	1 (2.6)	1	8 (5.0)	8
Related to IP	0		0		0		0	
Urinary tract infection	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Injury, poisoning and procedural complications	5 (6.3)	6	4 (9.8)	4	3 (7.7)	3	12 (7.5)	13
Administration related reaction	0		2 (4.9)	2	0		2 (1.3)	2
Related to IP	0		0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Arthropod bite	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Contusion	0		1 (2.4)	1	0		1 (0.6)	1
Related to IP	0		0		0		0	
Excoriation	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Laceration	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Ligament sprain	3 (3.8)	3	0		0		3 (1.9)	3
Related to IP	0		0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Muscle strain	0		0		2 (5.1)	2	2 (1.3)	2
Related to IP	0		0		0		0	
Thermal burn	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Wound	0		1 (2.4)	1	0		1 (0.6)	1
Related to IP	0		0		0		0	
Investigations	27 (33.8)	42	11 (26.8)	13	12 (30.8)	15	50 (31.3)	70
Alanine aminotransferase increased	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Aspartate aminotransferase increased	1 (1.3)	2	1 (2.4)	1	0		2 (1.3)	3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0		0	
Blood bilirubin increased	1 (1.3)	3	0		1 (2.6)	1	2 (1.3)	4
Related to IP	0		0		0		0	
Blood cholesterol increased	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Blood potassium increased	2 (2.5)	2	1 (2.4)	1	0		3 (1.9)	3
Related to IP	0		0		0		0	
Blood triglycerides increased	2 (2.5)	2	2 (4.9)	3	2 (5.1)	2	6 (3.8)	7
Related to IP	0		0		0		0	
Carbon monoxide diffusing capacity decreased	1 (1.3)	1	1 (2.4)	1	1 (2.6)	1	3 (1.9)	3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Expected	0		1 (2.4)	1	0		1 (0.6)	1
Not expected	1 (1.3)	1	0		0		1 (0.6)	1
Forced expiratory volume decreased	2 (2.5)	2	0		0		2 (1.3)	2
Related to IP	0		0		0		0	
Gamma-glutamyltransferase increased	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Haemoglobin decreased	11 (13.8)	14	4 (9.8)	5	6 (15.4)	8	21 (13.1)	27
Related to IP	0		0		0		0	
Lymphocyte count increased	6 (7.5)	7	2 (4.9)	2	1 (2.6)	1	9 (5.6)	10

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0		0	
Neutrophil count decreased	4 (5.0)	5	0		0		4 (2.5)	5
Related to IP	0		0		0		0	
Protein urine	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Vital capacity decreased	2 (2.5)	2	0		0		2 (1.3)	2
Related to IP	0		0		0		0	
Metabolism and nutrition disorders	2 (2.5)	3	0		2 (5.1)	2	4 (2.5)	5
Hyperglycaemia	0				1 (2.6)	1	1 (0.6)	1
Related to IP	0				0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Hypertriglyceridaemia	2 (2.5)	3			0		2 (1.3)	3
Related to IP	0				0		0	
Increased appetite	0				1 (2.6)	1	1 (0.6)	1
Related to IP	0				0		0	
Musculoskeletal and connective tissue disorders	2 (2.5)	3	0		1 (2.6)	1	3 (1.9)	4
Back pain	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Related to IP	0				0		0	
Muscle spasms	1 (1.3)	1			0		1 (0.6)	1
Related to IP	0				0		0	
Pain in extremity	1 (1.3)	1			0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0				0		0	
Nervous system disorders	7 (8.8)	7	1 (2.4)	1	4 (10.3)	6	12 (7.5)	14
Dizziness	1 (1.3)	1	0		2 (5.1)	2	3 (1.9)	3
Related to IP	0		0		0		0	
Headache	4 (5.0)	4	1 (2.4)	1	3 (7.7)	4	8 (5.0)	9
Related to IP	0		0		0		0	
Paraesthesia	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Presyncope	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Psychiatric disorders	1 (1.3)	1	1 (2.4)	1	3 (7.7)	5	5 (3.1)	7
Abnormal dreams	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Related to IP	0	0	0	0	0	0	0	0
Anxiety	0	0	0	0	1 (2.6)	1	1 (0.6)	1
Related to IP	0	0	0	0	0	0	0	0
Depressed mood	0	0	0	0	1 (2.6)	1	1 (0.6)	1
Related to IP	0	0	0	0	0	0	0	0
Insomnia	0	0	0	0	1 (2.6)	1	1 (0.6)	1
Related to IP	0	0	0	0	0	0	0	0
Nightmare	0	0	1 (2.4)	1	0	0	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0		0	
Restlessness	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Tension	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Renal and urinary disorders	1 (1.3)	1	0		3 (7.7)	3	4 (2.5)	4
Dysuria	0				1 (2.6)	1	1 (0.6)	1
Related to IP	0				0		0	
Proteinuria	0				1 (2.6)	1	1 (0.6)	1
Related to IP	0				0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Glycosuria	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Related to IP	0				0		0	
Reproductive system and breast disorders	1 (1.3)	1	0		0		1 (0.6)	1
Erectile dysfunction	1 (1.3)	1					1 (0.6)	1
Related to IP	0						0	
Respiratory, thoracic and mediastinal disorders	9 (11.3)	15	4 (9.8)	4	3 (7.7)	3	16 (10.0)	22
Cough	3 (3.8)	3	1 (2.4)	1	0		4 (2.5)	4
Related to IP	1 (1.3)	1	0		0		1 (0.6)	1
Not expected	1 (1.3)	1	0		0		1 (0.6)	1
Dyspnoea	1 (1.3)	1	0		0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0		0	
Nasal congestion	3 (3.8)	3	2 (4.9)	2	0		5 (3.1)	5
Related to IP	0		0		0		0	
Nasal discomfort	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Oropharyngeal pain	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3
Related to IP	0		0		0		0	
Pulmonary congestion	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Respiratory disorder	1 (1.3)	1	0		0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0		0	
Rhinitis allergic	0		1 (2.4)	1	0		1 (0.6)	1
Related to IP	0		0		0		0	
Rhinorrhoea	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Sinus congestion	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2
Related to IP	0		0		0		0	
Sneezing	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	1 (1.3)	1	0		0		1 (0.6)	1
Not expected	1 (1.3)	1	0		0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Upper-airway cough syndrome	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	1 (1.3)	1	0		0		1 (0.6)	1
Not expected	1 (1.3)	1	0		0		1 (0.6)	1
Skin and subcutaneous tissue disorders	3 (3.8)	5	1 (2.4)	2	2 (5.1)	2	6 (3.8)	9
Acne	2 (2.5)	2	0		0		2 (1.3)	2
Related to IP	0		0		0		0	
Cold sweat	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Erythema	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Pruritus	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Related to IP	0		0		0		0	
Rash	2 (2.5)	2	1 (2.4)	1	0		3 (1.9)	3
Related to IP	0		0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product (THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

Appendix 15.3.6.1

Study ID: ZRHM-REXA-08-US Program: t_ae_soc_ip1.sas Status: Final

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**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	23 (28.8)	39	11 (26.8)	14	13 (33.3)	27	47 (29.4)	80
Related to IP	5 (6.3)	5	1 (2.4)	1	0		6 (3.8)	6
Expected	0		1 (2.4)	1	0		1 (0.6)	1
Not expected	5 (6.3)	5	0		0		5 (3.1)	5
Blood and lymphatic system disorders	1 (1.3)	1	0		0		1 (0.6)	1
Anaemia	1 (1.3)	1					1 (0.6)	1
Related to IP	0						0	
Eye disorders	0		0		1 (2.6)	1	1 (0.6)	1
Scleral haemorrhage					1 (2.6)	1	1 (0.6)	1
Related to IP					0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Gastrointestinal disorders	9 (11.3)	10	2 (4.9)	2	3 (7.7)	3	14 (8.8)	15
Abdominal pain	0		1 (2.4)	1	0		1 (0.6)	1
Related to IP	0		0		0		0	
Constipation	2 (2.5)	2	0		0		2 (1.3)	2
Related to IP	0		0		0		0	
Dry mouth	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2
Related to IP	1 (1.3)	1	0		0		1 (0.6)	1
Not expected	1 (1.3)	1	0		0		1 (0.6)	1
Flatulence	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Lip dry	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Related to IP	0		0		0		0	
Nausea	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3
Related to IP	0		0		0		0	
Paraesthesia oral	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Salivary hypersecretion	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	1 (1.3)	1	0		0		1 (0.6)	1
Not expected	1 (1.3)	1	0		0		1 (0.6)	1
Toothache	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0		0	
General disorders and administration site conditions	0		0		1 (2.6)	1	1 (0.6)	1
Feeling hot					1 (2.6)	1	1 (0.6)	1
Related to IP					0		0	
Infections and infestations	1 (1.3)	1	2 (4.9)	2	0		3 (1.9)	3
Oral herpes	0		1 (2.4)	1			1 (0.6)	1
Related to IP	0		0				0	
Pharyngitis	1 (1.3)	1	0				1 (0.6)	1
Related to IP	0		0				0	
Upper respiratory tract infection	0		1 (2.4)	1			1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0				0	
Injury, poisoning and procedural complications	0		3 (7.3)	3	1 (2.6)	1	4 (2.5)	4
Administration related reaction			2 (4.9)	2	0		2 (1.3)	2
Related to IP			0		0		0	
Contusion			1 (2.4)	1	0		1 (0.6)	1
Related to IP			0		0		0	
Muscle strain			0		1 (2.6)	1	1 (0.6)	1
Related to IP			0		0		0	
Investigations	9 (11.3)	10	3 (7.3)	3	4 (10.3)	4	16 (10.0)	17
Blood potassium increased	0		1 (2.4)	1	0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0		0	
Blood triglycerides increased	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2
Related to IP	0		0		0		0	
Carbon monoxide diffusing capacity decreased	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Related to IP	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Expected	0		1 (2.4)	1	0		1 (0.6)	1
Not expected	1 (1.3)	1	0		0		1 (0.6)	1
Forced expiratory volume decreased	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Haemoglobin decreased	3 (3.8)	3	0		2 (5.1)	2	5 (3.1)	5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0		0	
Lymphocyte count increased	2 (2.5)	2	1 (2.4)	1	0		3 (1.9)	3
Related to IP	0		0		0		0	
Neutrophil count decreased	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Protein urine	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Vital capacity decreased	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Metabolism and nutrition disorders	0		0		1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product (THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Increased appetite Related to IP					1 (2.6) 0	1	1 (0.6) 0	1
Musculoskeletal and connective tissue disorders	2 (2.5)	3	0		1 (2.6)	1	3 (1.9)	4
Back pain	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Related to IP	0				0		0	
Muscle spasms	1 (1.3)	1			0		1 (0.6)	1
Related to IP	0				0		0	
Pain in extremity	1 (1.3)	1			0		1 (0.6)	1
Related to IP	0				0		0	
Nervous system disorders	6 (7.5)	6	0		3 (7.7)	5	9 (5.6)	11

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Dizziness	1 (1.3)	1			2 (5.1)	2	3 (1.9)	3
Related to IP	0				0		0	
Headache	3 (3.8)	3			2 (5.1)	3	5 (3.1)	6
Related to IP	0				0		0	
Paraesthesia	1 (1.3)	1			0		1 (0.6)	1
Related to IP	0				0		0	
Presyncope	1 (1.3)	1			0		1 (0.6)	1
Related to IP	0				0		0	
Psychiatric disorders	1 (1.3)	1	1 (2.4)	1	3 (7.7)	5	5 (3.1)	7
Abnormal dreams	1 (1.3)	1	0		0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0		0	
Anxiety	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Depressed mood	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Insomnia	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Nightmare	0		1 (2.4)	1	0		1 (0.6)	1
Related to IP	0		0		0		0	
Restlessness	0		0		1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0		0	
Tension	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Respiratory, thoracic and mediastinal disorders	4 (5.0)	6	1 (2.4)	1	3 (7.7)	3	8 (5.0)	10
Cough	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Dyspnoea	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Nasal congestion	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Related to IP	0		0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Nasal discomfort	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Oropharyngeal pain	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2
Related to IP	0		0		0		0	
Sinus congestion	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Sneezing	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	1 (1.3)	1	0		0		1 (0.6)	1
Not expected	1 (1.3)	1	0		0		1 (0.6)	1
Upper-airway cough syndrome	1 (1.3)	1	0		0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	1 (1.3)	1	0		0		1 (0.6)	1
Not expected	1 (1.3)	1	0		0		1 (0.6)	1
Skin and subcutaneous tissue disorders	1 (1.3)	1	1 (2.4)	2	2 (5.1)	2	4 (2.5)	5
Acne	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Cold sweat	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Erythema	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Pruritus	0		1 (2.4)	1	0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0		0	
Rash	0		1 (2.4)	1	0		1 (0.6)	1
Related to IP	0		0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

Appendix 15.3.6.1

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**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	41 (51.3)	74	14 (34.2)	18	14 (35.9)	22	69 (43.1)	114
Related to IP	2 (2.5)	2	0		0		2 (1.3)	2
Expected								
Not expected	2 (2.5)	2	0		0		2 (1.3)	2
Blood and lymphatic system disorders	0		0		1 (2.6)	1	1 (0.6)	1
Leukocytosis					1 (2.6)	1	1 (0.6)	1
Related to IP					0		0	
Ear and labyrinth disorders	0		0		1 (2.6)	1	1 (0.6)	1
Ear pain					1 (2.6)	1	1 (0.6)	1
Related to IP					0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Eye disorders	2 (2.5)	2	0		0		2 (1.3)	2
Conjunctivitis	1 (1.3)	1					1 (0.6)	1
Related to IP	0						0	
Eye pruritus	1 (1.3)	1					1 (0.6)	1
Related to IP	0						0	
Gastrointestinal disorders	7 (8.8)	10	0		0		7 (4.4)	10
Abdominal pain	1 (1.3)	1					1 (0.6)	1
Related to IP	0						0	
Constipation	1 (1.3)	1					1 (0.6)	1
Related to IP	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Diarrhoea	1 (1.3)	1					1 (0.6)	1
Related to IP	0						0	
Dry mouth	1 (1.3)	1					1 (0.6)	1
Related to IP	0						0	
Gingival bleeding	1 (1.3)	1					1 (0.6)	1
Related to IP	0						0	
Gingival pain	1 (1.3)	1					1 (0.6)	1
Related to IP	0						0	
Nausea	1 (1.3)	1					1 (0.6)	1
Related to IP	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Toothache	1 (1.3)	2					1 (0.6)	2
Related to IP	0						0	
Vomiting	1 (1.3)	1					1 (0.6)	1
Related to IP	0						0	
General disorders and administration site conditions	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3
Chest discomfort	1 (1.3)	1			0		1 (0.6)	1
Related to IP	0				0		0	
Non-cardiac chest pain	1 (1.3)	1			0		1 (0.6)	1
Related to IP	1 (1.3)	1			0		1 (0.6)	1
Not expected	1 (1.3)	1			0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Pyrexia	0				1 (2.6)	1	1 (0.6)	1
Related to IP	0				0		0	
Infections and infestations	4 (5.0)	4	3 (7.3)	3	1 (2.6)	1	8 (5.0)	8
Upper respiratory tract infection	3 (3.8)	3	3 (7.3)	3	1 (2.6)	1	7 (4.4)	7
Related to IP	0		0		0		0	
Urinary tract infection	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Injury, poisoning and procedural complications	5 (6.3)	6	1 (2.4)	1	2 (5.1)	2	8 (5.0)	9
Arthropod bite	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Excoriation	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Laceration	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Ligament sprain	3 (3.8)	3	0		0		3 (1.9)	3
Related to IP	0		0		0		0	
Muscle strain	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Thermal burn	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Wound	0		1 (2.4)	1	0		1 (0.6)	1
Related to IP	0		0		0		0	
Investigations	20 (25.0)	31	8 (19.5)	10	9 (23.1)	11	37 (23.1)	52
Alanine aminotransferase increased	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Aspartate aminotransferase increased	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Related to IP	0		0		0		0	
Blood bilirubin increased	1 (1.3)	3	0		1 (2.6)	1	2 (1.3)	4
Related to IP	0		0		0		0	
Blood cholesterol increased	0		0		1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product (THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0		0	
Blood potassium increased	2 (2.5)	2	0		0		2 (1.3)	2
Related to IP	0		0		0		0	
Blood triglycerides increased	1 (1.3)	1	2 (4.9)	3	1 (2.6)	1	4 (2.5)	5
Related to IP	0		0		0		0	
Carbon monoxide diffusing capacity decreased	0		0		1 (2.6)	1	1 (0.6)	1
Related to IP	0		0		0		0	
Forced expiratory volume decreased	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Gamma-glutamyltransferase increased	1 (1.3)	1	0		0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0		0	
Haemoglobin decreased	8 (10.0)	11	4 (9.8)	5	5 (12.8)	6	17 (10.6)	22
Related to IP	0		0		0		0	
Lymphocyte count increased	5 (6.3)	5	1 (2.4)	1	1 (2.6)	1	7 (4.4)	7
Related to IP	0		0		0		0	
Neutrophil count decreased	3 (3.8)	4	0		0		3 (1.9)	4
Related to IP	0		0		0		0	
Vital capacity decreased	1 (1.3)	1	0		0		1 (0.6)	1
Related to IP	0		0		0		0	
Metabolism and nutrition disorders	2 (2.5)	3	0		1 (2.6)	1	3 (1.9)	4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Hyperglycaemia	0				1 (2.6)	1	1 (0.6)	1
Related to IP	0				0		0	
Hypertriglyceridaemia	2 (2.5)	3			0		2 (1.3)	3
Related to IP	0				0		0	
Nervous system disorders	1 (1.3)	1	1 (2.4)	1	1 (2.6)	1	3 (1.9)	3
Headache	1 (1.3)	1	1 (2.4)	1	1 (2.6)	1	3 (1.9)	3
Related to IP	0		0		0		0	
Renal and urinary disorders	1 (1.3)	1	0		3 (7.7)	3	4 (2.5)	4
Dysuria	0				1 (2.6)	1	1 (0.6)	1
Related to IP	0				0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Proteinuria	0				1 (2.6)	1	1 (0.6)	1
Related to IP	0				0		0	
Glycosuria	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Related to IP	0				0		0	
Reproductive system and breast disorders	1 (1.3)	1	0		0		1 (0.6)	1
Erectile dysfunction	1 (1.3)	1					1 (0.6)	1
Related to IP	0						0	
Respiratory, thoracic and mediastinal disorders	5 (6.3)	9	3 (7.3)	3	0		8 (5.0)	12
Cough	2 (2.5)	2	1 (2.4)	1			3 (1.9)	3
Related to IP	1 (1.3)	1	0				1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product (THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Not expected	1 (1.3)	1	0				1 (0.6)	1
Nasal congestion	2 (2.5)	2	1 (2.4)	1			3 (1.9)	3
Related to IP	0		0				0	
Oropharyngeal pain	1 (1.3)	1	0				1 (0.6)	1
Related to IP	0		0				0	
Pulmonary congestion	1 (1.3)	1	0				1 (0.6)	1
Related to IP	0		0				0	
Respiratory disorder	1 (1.3)	1	0				1 (0.6)	1
Related to IP	0		0				0	
Rhinitis allergic	0		1 (2.4)	1			1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0				0	
Rhinorrhoea	1 (1.3)	1	0				1 (0.6)	1
Related to IP	0		0				0	
Sinus congestion	1 (1.3)	1	0				1 (0.6)	1
Related to IP	0		0				0	
Skin and subcutaneous tissue disorders	2 (2.5)	4	0		0		2 (1.3)	4
Acne	1 (1.3)	1					1 (0.6)	1
Related to IP	0						0	
Pruritus	1 (1.3)	1					1 (0.6)	1
Related to IP	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Rash	2 (2.5)	2					2 (1.3)	2
Related to IP	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

Appendix 15.3.6.1

Study ID: ZRHM-REXA-08-US Program: t_ae_soc_ip1.sas Status: Final

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**Table 15.2.6.5 Summary of Adverse Events by System Organ Class and Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population****Safety Time Period: Safety Follow-Up**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events

No adverse events related to study product exposure and expectedness were reported in Safety Follow-Up period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

Appendix 15.3.6.1

Study ID: ZRHM-REXA-08-US Program: t_ae_soc_ip1.sas Status: Final

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**Table 15.2.6.6 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population**

Within THS 2.2 (N=80)						
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	32 (47.8)	60	6 (60.0)	8	3 (100.0)	6
Related to IP	2 (3.0)	2	0		0	
Expected	0		0		0	
Not expected	2 (3.0)	2	0		0	
Eye disorders	2 (3.0)	2	0		0	
Conjunctivitis	1 (1.5)	1				
Related to IP	0					
Eye pruritus	1 (1.5)	1				
Related to IP	0					
Gastrointestinal disorders	5 (7.5)	8	2 (20.0)	2	0	
Abdominal pain	1 (1.5)	1	0			

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.6 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population**

Within THS 2.2 (N=80)						
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0			
Constipation	0		1 (10.0)	1		
Related to IP	0		0			
Diarrhoea	1 (1.5)	1	0			
Related to IP	0		0			
Dry mouth	1 (1.5)	1	0			
Related to IP	0		0			
Gingival bleeding	1 (1.5)	1	0			
Related to IP	0		0			
Gingival pain	1 (1.5)	1	0			
Related to IP	0		0			

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.6 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population**

Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)
	n(%)	Events	n(%)	Events	n(%) Events
Nausea	0		1 (10.0)	1	
Related to IP	0		0		
Toothache	1 (1.5)	2	0		
Related to IP	0		0		
Vomiting	1 (1.5)	1	0		
Related to IP	0		0		
General disorders and administration site conditions	2 (3.0)	2	0		0
Chest discomfort	1 (1.5)	1			
Related to IP	0				
Non-cardiac chest pain	1 (1.5)	1			
Related to IP	1 (1.5)	1			

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.6 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population**

Within THS 2.2 (N=80)						
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Not expected	1 (1.5)	1				
Infections and infestations	4 (6.0)	4	0		0	
Upper respiratory tract infection	3 (4.5)	3				
Related to IP	0					
Urinary tract infection	1 (1.5)	1				
Related to IP	0					
Injury, poisoning and procedural complications	2 (3.0)	2	1 (10.0)	1	2 (66.7)	3
Excoriation	0		0		1 (33.3)	1
Related to IP	0		0		0	
Laceration	1 (1.5)	1	0		0	
Related to IP	0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.6 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population**

Within THS 2.2 (N=80)						
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Ligament sprain	0		1 (10.0)	1	2 (66.7)	2
Related to IP	0		0		0	
Thermal burn	1 (1.5)	1	0		0	
Related to IP	0		0		0	
Investigations	16 (23.9)	24	3 (30.0)	4	1 (33.3)	3
Alanine aminotransferase increased	1 (1.5)	1	0		0	
Related to IP	0		0		0	
Aspartate aminotransferase increased	1 (1.5)	1	0		0	
Related to IP	0		0		0	
Blood bilirubin increased	1 (1.5)	3	0		0	
Related to IP	0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.6 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population**

Within THS 2.2 (N=80)						
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Blood potassium increased	2 (3.0)	2	0		0	
Related to IP	0		0		0	
Blood triglycerides increased	0		1 (10.0)	1	0	
Related to IP	0		0		0	
Forced expiratory volume decreased	0		0		1 (33.3)	1
Related to IP	0		0		0	
Gamma-glutamyltransferase increased	1 (1.5)	1	0		0	
Related to IP	0		0		0	
Haemoglobin decreased	7 (10.5)	10	1 (10.0)	1	0	
Related to IP	0		0		0	
Lymphocyte count increased	4 (6.0)	4	0		1 (33.3)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.6 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population**

Within THS 2.2 (N=80)						
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0		0		0	
Neutrophil count decreased	2 (3.0)	2	1 (10.0)	2	0	
Related to IP	0		0		0	
Vital capacity decreased	0		0		1 (33.3)	1
Related to IP	0		0		0	
Metabolism and nutrition disorders	2 (3.0)	3	0		0	
Hypertriglyceridaemia	2 (3.0)	3				
Related to IP	0					
Nervous system disorders	1 (1.5)	1	0		0	
Headache	1 (1.5)	1				
Related to IP	0					

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.6 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population**

Within THS 2.2 (N=80)						
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Renal and urinary disorders	1 (1.5)	1	0		0	
Glycosuria	1 (1.5)	1				
Related to IP	0					
Reproductive system and breast disorders	1 (1.5)	1	0		0	
Erectile dysfunction	1 (1.5)	1				
Related to IP	0					
Respiratory, thoracic and mediastinal disorders	5 (7.5)	9	0		0	
Cough	2 (3.0)	2				
Related to IP	1 (1.5)	1				
Not expected	1 (1.5)	1				
Nasal congestion	2 (3.0)	2				

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.6 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population**

Within THS 2.2 (N=80)						
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Related to IP	0					
Oropharyngeal pain	1 (1.5)	1				
Related to IP	0					
Pulmonary congestion	1 (1.5)	1				
Related to IP	0					
Respiratory disorder	1 (1.5)	1				
Related to IP	0					
Rhinorrhoea	1 (1.5)	1				
Related to IP	0					
Sinus congestion	1 (1.5)	1				
Related to IP	0					

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.6 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population**

Within THS 2.2 (N=80)						
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Skin and subcutaneous tissue disorders	1 (1.5)	3	1 (10.0)	1	0	
Acne	1 (1.5)	1	0			
Related to IP	0		0			
Pruritus	1 (1.5)	1	0			
Related to IP	0		0			
Rash	1 (1.5)	1	1 (10.0)	1		
Related to IP	0		0			

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.6 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population**

Within mCC (N=41)		CC (N=40)	
		n(%)	Events

No adverse events related to study product exposure and expectedness were reported

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.6 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness - Safety Population**

Within SA (N=39)					
Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
n(%)	Events	n(%)	Events	n(%)	Events

No adverse events related to study product exposure and expectedness were reported

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.7 Summary of Adverse Events Leading to Study Product Discontinuation, Interruption or Reduction by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	0		0		0		2 (40.0)	2	2 (1.2)	2
Injury, poisoning and procedural complications	0		0		0		1 (20.0)	1	1 (0.6)	1
Procedural complication							1 (20.0)	1	1 (0.6)	1
Nervous system disorders	0		0		0		1 (20.0)	1	1 (0.6)	1
Syncope							1 (20.0)	1	1 (0.6)	1

Note: Product Test refers to all subjects who tested the THS Product but were not randomized.

Note: The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.7 Summary of Adverse Events Leading to Study Product Discontinuation, Interruption or Reduction by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	1 (1.3)	1	0		0		1 (0.6)	1
General disorders and administration site conditions	1 (1.3)	1	0		0		1 (0.6)	1
Non-cardiac chest pain	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.7 Summary of Adverse Events Leading to Study Product Discontinuation, Interruption or Reduction by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events

No adverse events leading to Study Product Discontinuation, Interruption, or Reduction were reported during this Period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.7 Summary of Adverse Events Leading to Study Product Discontinuation, Interruption or Reduction by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	1 (1.3)	1	0		0		1 (0.6)	1
General disorders and administration site conditions	1 (1.3)	1	0		0		1 (0.6)	1
Non-cardiac chest pain	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.7 Summary of Adverse Events Leading to Study Product Discontinuation, Interruption or Reduction by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Safety Follow-Up**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events

No adverse events leading to Study Product Discontinuation, Interruption, or Reduction were reported during this Period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.8 Summary of Adverse Events Leading to Study Product Discontinuation, Interruption or Reduction by Product Use Category, System Organ Class and Preferred Term - Safety Population**

System Organ Class Preferred Term	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	1 (1.5)	1	0	0	0	0
General disorders and administration site conditions	1 (1.5)	1	0	0	0	0
Non-cardiac chest pain	1 (1.5)	1	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).



Table 15.2.6.8 Summary of Adverse Events Leading to Study Product Discontinuation, Interruption or Reduction by Product Use Category, System Organ Class and Preferred Term - Safety Population

Within mCC (N=41)		CC (N=41)	
System Organ Class	Preferred Term	n(%) Events	
		n(%)	Events

No adverse events leading to Study Product Discontinuation, Interruption or Reduction were reported during this Period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.8 Summary of Adverse Events Leading to Study Product Discontinuation, Interruption or Reduction by Product Use Category, System Organ Class and Preferred Term - Safety Population**

System Organ Class Preferred Term	Within SA (N=39)					
	Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
	n(%)		n(%)		n(%)	
	Events		Events		Events	

No adverse events leading to Study Product Discontinuation, Interruption or Reduction were reported during this Period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.9 Summary of Adverse Events Related to Study Procedure by System Organ Class and Preferred Term-Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	5 (6.3)	8	3 (7.3)	4	3 (7.7)	3	2 (40.0)	5	13 (7.9)	20
Gastrointestinal disorders	1 (1.3)	1	1 (2.4)	2	1 (2.6)	1	0		3 (1.8)	4
Abdominal pain	0		1 (2.4)	1	0				1 (0.6)	1
Dyspepsia	1 (1.3)	1	0		0				1 (0.6)	1
Flatulence	0		0		1 (2.6)	1			1 (0.6)	1
Nausea	0		1 (2.4)	1	0				1 (0.6)	1
General disorders and administration site conditions	1 (1.3)	2	1 (2.4)	1	0		0		2 (1.2)	3
Induration	1 (1.3)	1	0						1 (0.6)	1
Vessel puncture site bruise	1 (1.3)	1	0						1 (0.6)	1

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.9 Summary of Adverse Events Related to Study Procedure by System Organ Class and Preferred Term-Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Vessel puncture site haemorrhage	0		1 (2.4)	1					1 (0.6)	1
Injury, poisoning and procedural complications	0		1 (2.4)	1	1 (2.6)	1	1 (20.0)	3	3 (1.8)	5
Administration related reaction			1 (2.4)	1	0		0		1 (0.6)	1
Excoriation			0		0		1 (20.0)	2	1 (0.6)	2
Procedural complication			0		0		1 (20.0)	1	1 (0.6)	1
Procedural hypotension			0		1 (2.6)	1	0		1 (0.6)	1
Musculoskeletal and connective tissue disorders	1 (1.3)	1	0		0		0		1 (0.6)	1
Pain in extremity	1 (1.3)	1							1 (0.6)	1
Nervous system disorders	4 (5.0)	4	0		1 (2.6)	1	1 (20.0)	1	6 (3.6)	6

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.9 Summary of Adverse Events Related to Study Procedure by System Organ Class and Preferred Term-Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Presyncope	1 (1.3)	1			1 (2.6)	1	0		2 (1.2)	2
Syncope	3 (3.8)	3			0		1 (20.0)	1	4 (2.4)	4
Respiratory, thoracic and mediastinal disorders	0		0		0		1 (20.0)	1	1 (0.6)	1
Epistaxis							1 (20.0)	1	1 (0.6)	1

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.9 Summary of Adverse Events Related to Study Procedure by System Organ Class and Preferred Term-Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	3 (3.8)	3	2 (4.9)	2	2 (5.1)	2	7 (4.4)	7
Gastrointestinal disorders	1 (1.3)	1	0		0		1 (0.6)	1
Nausea	1 (1.3)	1					1 (0.6)	1
Injury, poisoning and procedural complications	0		2 (4.9)	2	0		2 (1.3)	2
Administration related reaction			2 (4.9)	2			2 (1.3)	2
Nervous system disorders	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3
Dizziness	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Paraesthesia	1 (1.3)	1			0		1 (0.6)	1
Respiratory, thoracic and mediastinal disorders	0		0		1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.9 Summary of Adverse Events Related to Study Procedure by System Organ Class and Preferred Term-Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Nasal discomfort					1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.9 Summary of Adverse Events Related to Study Procedure by System Organ Class and Preferred Term-Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	2 (2.5)	2	2 (4.9)	2	2 (5.1)	2	6 (3.8)	6
Injury, poisoning and procedural complications	0		2 (4.9)	2	0		2 (1.3)	2
Administration related reaction			2 (4.9)	2			2 (1.3)	2
Nervous system disorders	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3
Dizziness	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Paraesthesia	1 (1.3)	1			0		1 (0.6)	1
Respiratory, thoracic and mediastinal disorders	0		0		1 (2.6)	1	1 (0.6)	1
Nasal discomfort					1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.9 Summary of Adverse Events Related to Study Procedure by System Organ Class and Preferred Term-Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	1 (1.3)	1	0		0		1 (0.6)	1
Gastrointestinal disorders	1 (1.3)	1	0		0		1 (0.6)	1
Nausea	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.9 Summary of Adverse Events Related to Study Procedure by System Organ Class and Preferred Term-Safety Population****Safety Time Period: Safety Follow-Up**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events

No adverse events were reported during this period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol
Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	33 (41.3)	38	11 (26.8)	16	14 (35.9)	18	4 (80.0)	12	62 (37.6)	84
Mild	27 (33.8)	31	8 (19.5)	12	11 (28.2)	15	3 (60.0)	8	49 (29.7)	66
Moderate	7 (8.8)	7	4 (9.8)	4	3 (7.7)	3	1 (20.0)	1	15 (9.1)	15
Severe	0		0		0		2 (40.0)	3	2 (1.2)	3
Eye disorders	1 (1.3)	1	0		0		0		1 (0.6)	1
Conjunctival hyperaemia	1 (1.3)	1							1 (0.6)	1
Mild	1 (1.3)	1							1 (0.6)	1
Moderate	0								0	
Severe	0								0	
Gastrointestinal disorders	4 (5.0)	4	3 (7.3)	5	2 (5.1)	3	1 (20.0)	2	10 (6.1)	14

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product (THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Abdominal pain	0		1 (2.4)	1	0		0		1 (0.6)	1
Mild			1 (2.4)	1					1 (0.6)	1
Moderate			0						0	
Severe			0						0	
Constipation	2 (2.5)	2	1 (2.4)	1	0		0		3 (1.8)	3
Mild	2 (2.5)	2	1 (2.4)	1					3 (1.8)	3
Moderate	0		0						0	
Severe	0		0						0	
Dyspepsia	1 (1.3)	1	0		0		0		1 (0.6)	1
Mild	1 (1.3)	1							1 (0.6)	1

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0								0	
Severe	0								0	
Flatulence	1 (1.3)	1	0		1 (2.6)	1	0		2 (1.2)	2
Mild	1 (1.3)	1			1 (2.6)	1			2 (1.2)	2
Moderate	0				0				0	
Severe	0				0				0	
Nausea	0		2 (4.9)	2	1 (2.6)	1	1 (20.0)	1	4 (2.4)	4
Mild			2 (4.9)	2	1 (2.6)	1	1 (20.0)	1	4 (2.4)	4
Moderate			0		0		0		0	
Severe			0		0		0		0	

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product (THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Vomiting	0		1 (2.4)	1	1 (2.6)	1	1 (20.0)	1	3 (1.8)	3
Mild			1 (2.4)	1	1 (2.6)	1	1 (20.0)	1	3 (1.8)	3
Moderate			0		0		0		0	
Severe			0		0		0		0	
General disorders and administration site conditions	1 (1.3)	2	1 (2.4)	1	0		0		2 (1.2)	3
Induration	1 (1.3)	1	0						1 (0.6)	1
Mild	1 (1.3)	1							1 (0.6)	1
Moderate	0								0	
Severe	0								0	
Vessel puncture site bruise	1 (1.3)	1	0						1 (0.6)	1

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild	1 (1.3)	1							1 (0.6)	1
Moderate	0								0	
Severe	0								0	
Vessel puncture site haemorrhage	0		1 (2.4)	1					1 (0.6)	1
Mild			1 (2.4)	1					1 (0.6)	1
Moderate			0						0	
Severe			0						0	
Infections and infestations	0		0		0		1 (20.0)	1	1 (0.6)	1
Sinusitis							1 (20.0)	1	1 (0.6)	1
Mild							0		0	

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate							0		0	
Severe							1 (20.0)	1	1 (0.6)	1
Injury, poisoning and procedural complications	0		1 (2.4)	1	2 (5.1)	2	1 (20.0)	3	4 (2.4)	6
Administration related reaction			1 (2.4)	1	0		0		1 (0.6)	1
Mild			0						0	
Moderate			1 (2.4)	1					1 (0.6)	1
Severe			0						0	
Excoriation			0		1 (2.6)	1	1 (20.0)	2	2 (1.2)	3
Mild					1 (2.6)	1	1 (20.0)	2	2 (1.2)	3
Moderate					0		0		0	

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product (THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe					0		0		0	
Procedural complication			0		0		1 (20.0)	1	1 (0.6)	1
Mild							0		0	
Moderate							1 (20.0)	1	1 (0.6)	1
Severe							0		0	
Procedural hypotension			0		1 (2.6)	1	0		1 (0.6)	1
Mild					0				0	
Moderate					1 (2.6)	1			1 (0.6)	1
Severe					0				0	
Investigations	7 (8.8)	7	5 (12.2)	5	3 (7.7)	3	1 (20.0)	1	16 (9.7)	16

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Blood creatinine increased	0		1 (2.4)	1	0		0		1 (0.6)	1
Mild			1 (2.4)	1					1 (0.6)	1
Moderate			0						0	
Severe			0						0	
Blood pressure increased	0		0		0		1 (20.0)	1	1 (0.6)	1
Mild							1 (20.0)	1	1 (0.6)	1
Moderate							0		0	
Severe							0		0	
Blood triglycerides increased	1 (1.3)	1	0		0		0		1 (0.6)	1
Mild	1 (1.3)	1							1 (0.6)	1

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0								0	
Severe	0								0	
Carbon monoxide diffusing capacity decreased	2 (2.5)	2	1 (2.4)	1	1 (2.6)	1	0		4 (2.4)	4
Mild	2 (2.5)	2	1 (2.4)	1	1 (2.6)	1			4 (2.4)	4
Moderate	0		0		0				0	
Severe	0		0		0				0	
Haemoglobin decreased	1 (1.3)	1	0		0		0		1 (0.6)	1
Mild	1 (1.3)	1							1 (0.6)	1
Moderate	0								0	
Severe	0								0	

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product (THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Lymphocyte count increased	2 (2.5)	2	3 (7.3)	3	2 (5.1)	2	0		7 (4.2)	7
Mild	1 (1.3)	1	0		0				1 (0.6)	1
Moderate	1 (1.3)	1	3 (7.3)	3	2 (5.1)	2			6 (3.6)	6
Severe	0		0		0				0	
Neutrophil count decreased	1 (1.3)	1	0		0		0		1 (0.6)	1
Mild	0								0	
Moderate	1 (1.3)	1							1 (0.6)	1
Severe	0								0	
Metabolism and nutrition disorders	4 (5.0)	4	0		0		1 (20.0)	1	5 (3.0)	5
Diabetic ketoacidosis	0						1 (20.0)	1	1 (0.6)	1

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild							0		0	
Moderate							0		0	
Severe							1 (20.0)	1	1 (0.6)	1
Hypercholesterolaemia	1 (1.3)	1					0		1 (0.6)	1
Mild	0								0	
Moderate	1 (1.3)	1							1 (0.6)	1
Severe	0								0	
Hypertriglyceridaemia	3 (3.8)	3					0		3 (1.8)	3
Mild	0								0	
Moderate	3 (3.8)	3							3 (1.8)	3

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0								0	
Musculoskeletal and connective tissue disorders	2 (2.5)	2	0		1 (2.6)	1	0		3 (1.8)	3
Arthralgia	1 (1.3)	1			0				1 (0.6)	1
Mild	1 (1.3)	1							1 (0.6)	1
Moderate	0								0	
Severe	0								0	
Back pain	0				1 (2.6)	1			1 (0.6)	1
Mild					1 (2.6)	1			1 (0.6)	1
Moderate					0				0	
Severe					0				0	

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Pain in extremity	1 (1.3)	1			0				1 (0.6)	1
Mild	1 (1.3)	1							1 (0.6)	1
Moderate	0								0	
Severe	0								0	
Nervous system disorders	15 (18.8)	15	4 (9.8)	4	6 (15.4)	6	3 (60.0)	3	28 (17.0)	28
Dizziness	2 (2.5)	2	0		1 (2.6)	1	0		3 (1.8)	3
Mild	2 (2.5)	2			1 (2.6)	1			3 (1.8)	3
Moderate	0				0				0	
Severe	0				0				0	
Headache	9 (11.3)	9	4 (9.8)	4	4 (10.3)	4	2 (40.0)	2	19 (11.5)	19

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild	8 (10.0)	8	4 (9.8)	4	4 (10.3)	4	2 (40.0)	2	18 (10.9)	18
Moderate	1 (1.3)	1	0		0		0		1 (0.6)	1
Severe	0		0		0		0		0	
Presyncope	1 (1.3)	1	0		1 (2.6)	1	0		2 (1.2)	2
Mild	1 (1.3)	1			1 (2.6)	1			2 (1.2)	2
Moderate	0				0				0	
Severe	0				0				0	
Syncope	3 (3.8)	3	0		0		1 (20.0)	1	4 (2.4)	4
Mild	3 (3.8)	3					0		3 (1.8)	3
Moderate	0						0		0	

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0						1 (20.0)	1	1 (0.6)	1
Psychiatric disorders	1 (1.3)	1	0		0		0		1 (0.6)	1
Anxiety	1 (1.3)	1							1 (0.6)	1
Mild	1 (1.3)	1							1 (0.6)	1
Moderate	0								0	
Severe	0								0	
Respiratory, thoracic and mediastinal disorders	1 (1.3)	1	0		1 (2.6)	1	1 (20.0)	1	3 (1.8)	3
Cough	1 (1.3)	1			0		0		1 (0.6)	1
Mild	1 (1.3)	1							1 (0.6)	1
Moderate	0								0	

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0								0	
Epistaxis	0				0		1 (20.0)	1	1 (0.6)	1
Mild							1 (20.0)	1	1 (0.6)	1
Moderate							0		0	
Severe							0		0	
Throat irritation	0				1 (2.6)	1	0		1 (0.6)	1
Mild					1 (2.6)	1			1 (0.6)	1
Moderate					0				0	
Severe					0				0	
Skin and subcutaneous tissue disorders	1 (1.3)	1	0		1 (2.6)	2	0		2 (1.2)	3

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Pruritus	0				1 (2.6)	1			1 (0.6)	1
Mild					1 (2.6)	1			1 (0.6)	1
Moderate					0				0	
Severe					0				0	
Skin irritation	1 (1.3)	1			0				1 (0.6)	1
Mild	1 (1.3)	1							1 (0.6)	1
Moderate	0								0	
Severe	0								0	
Urticaria	0				1 (2.6)	1			1 (0.6)	1
Mild					1 (2.6)	1			1 (0.6)	1

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product (THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Pre-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate					0				0	
Severe					0				0	

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

Appendix 15.3.6.1

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**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Adverse event	52 (65.0)	114	20 (48.8)	32	23 (59.0)	49	95 (59.4)	195
Mild	33 (41.3)	77	16 (39.0)	22	16 (41.0)	34	65 (40.6)	133
Moderate	23 (28.8)	29	8 (19.5)	8	10 (25.6)	13	41 (25.6)	50
Severe	8 (10.0)	8	2 (4.9)	2	2 (5.1)	2	12 (7.5)	12
Blood and lymphatic system disorders	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2
Anaemia	1 (1.3)	1			0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Leukocytosis	0				1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Ear and labyrinth disorders	0		0		1 (2.6)	1	1 (0.6)	1
Ear pain					1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Eye disorders	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3
Conjunctivitis	1 (1.3)	1			0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product (THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Eye pruritus	1 (1.3)	1			0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Scleral haemorrhage	0				1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe					0		0	
Gastrointestinal disorders	15 (18.8)	20	2 (4.9)	2	3 (7.7)	3	20 (12.5)	25
Abdominal pain	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Mild	1 (1.3)	1	1 (2.4)	1			2 (1.3)	2
Moderate	0		0				0	
Severe	0		0				0	
Constipation	3 (3.8)	3	0		0		3 (1.9)	3
Mild	3 (3.8)	3					3 (1.9)	3
Moderate	0						0	
Severe	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Diarrhoea	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Dry mouth	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3
Mild	2 (2.5)	2			1 (2.6)	1	3 (1.9)	3
Moderate	0				0		0	
Severe	0				0		0	
Flatulence	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0						0	
Severe	0						0	
Gingival bleeding	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Gingival pain	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Lip dry	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Mild	1 (1.3)	1	1 (2.4)	1			2 (1.3)	2
Moderate	0		0				0	
Severe	0		0				0	
Nausea	3 (3.8)	3	0		1 (2.6)	1	4 (2.5)	4
Mild	3 (3.8)	3			1 (2.6)	1	4 (2.5)	4
Moderate	0				0		0	
Severe	0				0		0	
Paraesthesia oral	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0						0	
Severe	0						0	
Salivary hypersecretion	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Toothache	2 (2.5)	3	0		1 (2.6)	1	3 (1.9)	4
Mild	2 (2.5)	2			0		2 (1.3)	2
Moderate	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Severe	0				0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Vomiting	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
General disorders and administration site conditions	2 (2.5)	2	0		2 (5.1)	2	4 (2.5)	4
Chest discomfort	1 (1.3)	1			0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Feeling hot	0				1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Non-cardiac chest pain	1 (1.3)	1			0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Pyrexia	0				1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe					0		0	
Infections and infestations	5 (6.3)	5	5 (12.2)	5	1 (2.6)	1	11 (6.9)	11
Oral herpes	0		1 (2.4)	1	0		1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0				0	
Severe			0				0	
Pharyngitis	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Upper respiratory tract infection	3 (3.8)	3	4 (9.8)	4	1 (2.6)	1	8 (5.0)	8
Mild	3 (3.8)	3	4 (9.8)	4	1 (2.6)	1	8 (5.0)	8
Moderate	0		0		0		0	
Severe	0		0		0		0	
Urinary tract infection	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Injury, poisoning and procedural complications	5 (6.3)	6	4 (9.8)	4	3 (7.7)	3	12 (7.5)	13
Administration related reaction	0		2 (4.9)	2	0		2 (1.3)	2

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild			2 (4.9)	2			2 (1.3)	2
Moderate			0				0	
Severe			0				0	
Arthropod bite	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Contusion	0		1 (2.4)	1	0		1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0				0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe			0				0	
Excoriation	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Laceration	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Ligament sprain	3 (3.8)	3	0		0		3 (1.9)	3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	2 (2.5)	2					2 (1.3)	2
Severe	0						0	
Muscle strain	0		0		2 (5.1)	2	2 (1.3)	2
Mild					2 (5.1)	2	2 (1.3)	2
Moderate					0		0	
Severe					0		0	
Thermal burn	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0						0	
Wound	0		1 (2.4)	1	0		1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0				0	
Severe			0				0	
Investigations	27 (33.8)	42	11 (26.8)	13	12 (30.8)	15	50 (31.3)	70
Alanine aminotransferase increased	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Aspartate aminotransferase increased	1 (1.3)	2	1 (2.4)	1	0		2 (1.3)	3
Mild	1 (1.3)	1	0				1 (0.6)	1
Moderate	1 (1.3)	1	1 (2.4)	1			2 (1.3)	2
Severe	0		0				0	
Blood bilirubin increased	1 (1.3)	3	0		1 (2.6)	1	2 (1.3)	4
Mild	0				1 (2.6)	1	1 (0.6)	1
Moderate	1 (1.3)	3			0		1 (0.6)	3
Severe	0				0		0	
Blood cholesterol increased	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate					0		0	
Severe					0		0	
Blood potassium increased	2 (2.5)	2	1 (2.4)	1	0		3 (1.9)	3
Mild	1 (1.3)	1	0				1 (0.6)	1
Moderate	1 (1.3)	1	1 (2.4)	1			2 (1.3)	2
Severe	0		0				0	
Blood triglycerides increased	2 (2.5)	2	2 (4.9)	3	2 (5.1)	2	6 (3.8)	7
Mild	0		1 (2.4)	1	0		1 (0.6)	1
Moderate	2 (2.5)	2	2 (4.9)	2	2 (5.1)	2	6 (3.8)	6
Severe	0		0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Carbon monoxide diffusing capacity decreased	1 (1.3)	1	1 (2.4)	1	1 (2.6)	1	3 (1.9)	3
Mild	1 (1.3)	1	1 (2.4)	1	1 (2.6)	1	3 (1.9)	3
Moderate	0		0		0		0	
Severe	0		0		0		0	
Forced expiratory volume decreased	2 (2.5)	2	0		0		2 (1.3)	2
Mild	2 (2.5)	2					2 (1.3)	2
Moderate	0						0	
Severe	0						0	
Gamma-glutamyltransferase increased	1 (1.3)	1	0		0		1 (0.6)	1
Mild	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0						0	
Severe	1 (1.3)	1					1 (0.6)	1
Haemoglobin decreased	11 (13.8)	14	4 (9.8)	5	6 (15.4)	8	21 (13.1)	27
Mild	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Moderate	7 (8.8)	8	2 (4.9)	2	5 (12.8)	6	14 (8.8)	16
Severe	5 (6.3)	5	2 (4.9)	2	2 (5.1)	2	9 (5.6)	9
Lymphocyte count increased	6 (7.5)	7	2 (4.9)	2	1 (2.6)	1	9 (5.6)	10
Mild	0		0		0		0	
Moderate	6 (7.5)	7	2 (4.9)	2	1 (2.6)	1	9 (5.6)	10
Severe	0		0		0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Neutrophil count decreased	4 (5.0)	5	0		0		4 (2.5)	5
Mild	2 (2.5)	3					2 (1.3)	3
Moderate	2 (2.5)	2					2 (1.3)	2
Severe	0						0	
Protein urine	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Vital capacity decreased	2 (2.5)	2	0		0		2 (1.3)	2
Mild	2 (2.5)	2					2 (1.3)	2

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0						0	
Severe	0						0	
Metabolism and nutrition disorders	2 (2.5)	3	0		2 (5.1)	2	4 (2.5)	5
Hyperglycaemia	0				1 (2.6)	1	1 (0.6)	1
Mild					0		0	
Moderate					1 (2.6)	1	1 (0.6)	1
Severe					0		0	
Hypertriglyceridaemia	2 (2.5)	3			0		2 (1.3)	3
Mild	0						0	
Moderate	2 (2.5)	2					2 (1.3)	2

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	1 (1.3)	1					1 (0.6)	1
Increased appetite	0				1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Musculoskeletal and connective tissue disorders	2 (2.5)	3	0		1 (2.6)	1	3 (1.9)	4
Back pain	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Mild	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Moderate	0				0		0	
Severe	0				0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Muscle spasms	1 (1.3)	1			0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Pain in extremity	1 (1.3)	1			0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Nervous system disorders	7 (8.8)	7	1 (2.4)	1	4 (10.3)	6	12 (7.5)	14
Dizziness	1 (1.3)	1	0		2 (5.1)	2	3 (1.9)	3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild	1 (1.3)	1			2 (5.1)	2	3 (1.9)	3
Moderate	0				0		0	
Severe	0				0		0	
Headache	4 (5.0)	4	1 (2.4)	1	3 (7.7)	4	8 (5.0)	9
Mild	4 (5.0)	4	1 (2.4)	1	3 (7.7)	4	8 (5.0)	9
Moderate	0		0		0		0	
Severe	0		0		0		0	
Paraesthesia	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0						0	
Presyncope	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Psychiatric disorders	1 (1.3)	1	1 (2.4)	1	3 (7.7)	5	5 (3.1)	7
Abnormal dreams	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Anxiety	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Depressed mood	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Insomnia	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate					0		0	
Severe					0		0	
Nightmare	0		1 (2.4)	1	0		1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0				0	
Severe			0				0	
Restlessness	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Tension	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Renal and urinary disorders	1 (1.3)	1	0		3 (7.7)	3	4 (2.5)	4
Dysuria	0				1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Proteinuria	0				1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild					0		0	
Moderate					1 (2.6)	1	1 (0.6)	1
Severe					0		0	
Glycosuria	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Mild	0				0		0	
Moderate	0				1 (2.6)	1	1 (0.6)	1
Severe	1 (1.3)	1			0		1 (0.6)	1
Reproductive system and breast disorders	1 (1.3)	1	0		0		1 (0.6)	1
Erectile dysfunction	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0						0	
Severe	0						0	
Respiratory, thoracic and mediastinal disorders	9 (11.3)	15	4 (9.8)	4	3 (7.7)	3	16 (10.0)	22
Cough	3 (3.8)	3	1 (2.4)	1	0		4 (2.5)	4
Mild	3 (3.8)	3	1 (2.4)	1			4 (2.5)	4
Moderate	0		0				0	
Severe	0		0				0	
Dyspnoea	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0						0	
Nasal congestion	3 (3.8)	3	2 (4.9)	2	0		5 (3.1)	5
Mild	3 (3.8)	3	2 (4.9)	2			5 (3.1)	5
Moderate	0		0				0	
Severe	0		0				0	
Nasal discomfort	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Oropharyngeal pain	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild	2 (2.5)	2			1 (2.6)	1	3 (1.9)	3
Moderate	0				0		0	
Severe	0				0		0	
Pulmonary congestion	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Respiratory disorder	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0						0	
Rhinitis allergic	0		1 (2.4)	1	0		1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0				0	
Severe			0				0	
Rhinorrhoea	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Sinus congestion	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Moderate	0				0		0	
Severe	0				0		0	
Sneezing	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Upper-airway cough syndrome	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0						0	
Skin and subcutaneous tissue disorders	3 (3.8)	5	1 (2.4)	2	2 (5.1)	2	6 (3.8)	9
Acne	2 (2.5)	2	0		0		2 (1.3)	2
Mild	2 (2.5)	2					2 (1.3)	2
Moderate	0						0	
Severe	0						0	
Cold sweat	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Erythema	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Pruritus	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Mild	1 (1.3)	1	1 (2.4)	1			2 (1.3)	2
Moderate	0		0				0	
Severe	0		0				0	
Rash	2 (2.5)	2	1 (2.4)	1	0		3 (1.9)	3
Mild	2 (2.5)	2	1 (2.4)	1			3 (1.9)	3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Post-Randomization Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0		0				0	
Severe	0		0				0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

Appendix 15.3.6.1

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**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Adverse event	23 (28.8)	39	11 (26.8)	14	13 (33.3)	27	47 (29.4)	80
Mild	18 (22.5)	33	10 (24.4)	12	9 (23.1)	23	37 (23.1)	68
Moderate	6 (7.5)	6	2 (4.9)	2	4 (10.3)	4	12 (7.5)	12
Severe	0		0		0		0	
Blood and lymphatic system disorders	1 (1.3)	1	0		0		1 (0.6)	1
Anaemia	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Eye disorders	0		0		1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Scleral haemorrhage					1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Gastrointestinal disorders	9 (11.3)	10	2 (4.9)	2	3 (7.7)	3	14 (8.8)	15
Abdominal pain	0		1 (2.4)	1	0		1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0				0	
Severe			0				0	
Constipation	2 (2.5)	2	0		0		2 (1.3)	2

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild	2 (2.5)	2					2 (1.3)	2
Moderate	0						0	
Severe	0						0	
Dry mouth	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2
Mild	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Moderate	0				0		0	
Severe	0				0		0	
Flatulence	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0						0	
Lip dry	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Mild	1 (1.3)	1	1 (2.4)	1			2 (1.3)	2
Moderate	0		0				0	
Severe	0		0				0	
Nausea	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3
Mild	2 (2.5)	2			1 (2.6)	1	3 (1.9)	3
Moderate	0				0		0	
Severe	0				0		0	
Paraesthesia oral	1 (1.3)	1	0		0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Salivary hypersecretion	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Toothache	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2
Mild	1 (1.3)	1			0		1 (0.6)	1
Moderate	0				1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0				0		0	
General disorders and administration site conditions	0		0		1 (2.6)	1	1 (0.6)	1
Feeling hot					1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Infections and infestations	1 (1.3)	1	2 (4.9)	2	0		3 (1.9)	3
Oral herpes	0		1 (2.4)	1			1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0				0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe			0				0	
Pharyngitis	1 (1.3)	1	0				1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Upper respiratory tract infection	0		1 (2.4)	1			1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0				0	
Severe			0				0	
Injury, poisoning and procedural complications	0		3 (7.3)	3	1 (2.6)	1	4 (2.5)	4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Administration related reaction			2 (4.9)	2	0		2 (1.3)	2
Mild			2 (4.9)	2			2 (1.3)	2
Moderate			0				0	
Severe			0				0	
Contusion			1 (2.4)	1	0		1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0				0	
Severe			0				0	
Muscle strain			0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate					0		0	
Severe					0		0	
Investigations	9 (11.3)	10	3 (7.3)	3	4 (10.3)	4	16 (10.0)	17
Blood potassium increased	0		1 (2.4)	1	0		1 (0.6)	1
Mild			0				0	
Moderate			1 (2.4)	1			1 (0.6)	1
Severe			0				0	
Blood triglycerides increased	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2
Mild	0				0		0	
Moderate	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0				0		0	
Carbon monoxide diffusing capacity decreased	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Mild	1 (1.3)	1	1 (2.4)	1			2 (1.3)	2
Moderate	0		0				0	
Severe	0		0				0	
Forced expiratory volume decreased	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Haemoglobin decreased	3 (3.8)	3	0		2 (5.1)	2	5 (3.1)	5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild	1 (1.3)	1			0		1 (0.6)	1
Moderate	2 (2.5)	2			2 (5.1)	2	4 (2.5)	4
Severe	0				0		0	
Lymphocyte count increased	2 (2.5)	2	1 (2.4)	1	0		3 (1.9)	3
Mild	0		0				0	
Moderate	2 (2.5)	2	1 (2.4)	1			3 (1.9)	3
Severe	0		0				0	
Neutrophil count decreased	1 (1.3)	1	0		0		1 (0.6)	1
Mild	0						0	
Moderate	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0						0	
Protein urine	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Vital capacity decreased	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Metabolism and nutrition disorders	0		0		1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Increased appetite					1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Musculoskeletal and connective tissue disorders	2 (2.5)	3	0		1 (2.6)	1	3 (1.9)	4
Back pain	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Mild	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Moderate	0				0		0	
Severe	0				0		0	
Muscle spasms	1 (1.3)	1			0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Pain in extremity	1 (1.3)	1			0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Nervous system disorders	6 (7.5)	6	0		3 (7.7)	5	9 (5.6)	11
Dizziness	1 (1.3)	1			2 (5.1)	2	3 (1.9)	3
Mild	1 (1.3)	1			2 (5.1)	2	3 (1.9)	3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0				0		0	
Severe	0				0		0	
Headache	3 (3.8)	3			2 (5.1)	3	5 (3.1)	6
Mild	3 (3.8)	3			2 (5.1)	3	5 (3.1)	6
Moderate	0				0		0	
Severe	0				0		0	
Paraesthesia	1 (1.3)	1			0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Presyncope	1 (1.3)	1			0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Psychiatric disorders	1 (1.3)	1	1 (2.4)	1	3 (7.7)	5	5 (3.1)	7
Abnormal dreams	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Anxiety	0		0		1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Depressed mood	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Insomnia	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe					0		0	
Nightmare	0		1 (2.4)	1	0		1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0				0	
Severe			0				0	
Restlessness	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Tension	0		0		1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Respiratory, thoracic and mediastinal disorders	4 (5.0)	6	1 (2.4)	1	3 (7.7)	3	8 (5.0)	10
Cough	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Dyspnoea	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product (THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0						0	
Severe	0						0	
Nasal congestion	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Mild	1 (1.3)	1	1 (2.4)	1			2 (1.3)	2
Moderate	0		0				0	
Severe	0		0				0	
Nasal discomfort	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Oropharyngeal pain	1 (1.3)	1	0		1 (2.6)	1	2 (1.3)	2
Mild	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Moderate	0				0		0	
Severe	0				0		0	
Sinus congestion	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Sneezing	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0						0	
Severe	0						0	
Upper-airway cough syndrome	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Skin and subcutaneous tissue disorders	1 (1.3)	1	1 (2.4)	2	2 (5.1)	2	4 (2.5)	5
Acne	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0						0	
Cold sweat	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Erythema	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Pruritus	0		1 (2.4)	1	0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Confinement Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0				0	
Severe			0				0	
Rash	0		1 (2.4)	1	0		1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0				0	
Severe			0				0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Adverse event	41 (51.3)	74	14 (34.2)	18	14 (35.9)	22	69 (43.1)	114
Mild	24 (30.0)	43	10 (24.4)	10	10 (25.6)	11	44 (27.5)	64
Moderate	18 (22.5)	23	6 (14.6)	6	7 (18.0)	9	31 (19.4)	38
Severe	8 (10.0)	8	2 (4.9)	2	2 (5.1)	2	12 (7.5)	12
Blood and lymphatic system disorders	0		0		1 (2.6)	1	1 (0.6)	1
Leukocytosis					1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Ear and labyrinth disorders	0		0		1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Ear pain					1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Eye disorders	2 (2.5)	2	0		0		2 (1.3)	2
Conjunctivitis	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Eye pruritus	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Gastrointestinal disorders	7 (8.8)	10	0		0		7 (4.4)	10
Abdominal pain	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Constipation	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0						0	
Severe	0						0	
Diarrhoea	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Dry mouth	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Gingival bleeding	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Gingival pain	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Nausea	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0						0	
Severe	0						0	
Toothache	1 (1.3)	2					1 (0.6)	2
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	1 (1.3)	1					1 (0.6)	1
Severe	0						0	
Vomiting	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
General disorders and administration site conditions	2 (2.5)	2	0		1 (2.6)	1	3 (1.9)	3
Chest discomfort	1 (1.3)	1			0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Non-cardiac chest pain	1 (1.3)	1			0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Pyrexia	0				1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Infections and infestations	4 (5.0)	4	3 (7.3)	3	1 (2.6)	1	8 (5.0)	8
Upper respiratory tract infection	3 (3.8)	3	3 (7.3)	3	1 (2.6)	1	7 (4.4)	7
Mild	3 (3.8)	3	3 (7.3)	3	1 (2.6)	1	7 (4.4)	7
Moderate	0		0		0		0	
Severe	0		0		0		0	
Urinary tract infection	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product (THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0						0	
Severe	0						0	
Injury, poisoning and procedural complications	5 (6.3)	6	1 (2.4)	1	2 (5.1)	2	8 (5.0)	9
Arthropod bite	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Excoriation	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0						0	
Laceration	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Ligament sprain	3 (3.8)	3	0		0		3 (1.9)	3
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	2 (2.5)	2					2 (1.3)	2
Severe	0						0	
Muscle strain	0		0		1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Thermal burn	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Wound	0		1 (2.4)	1	0		1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0				0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe			0				0	
Investigations	20 (25.0)	31	8 (19.5)	10	9 (23.1)	11	37 (23.1)	52
Alanine aminotransferase increased	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Aspartate aminotransferase increased	1 (1.3)	1	1 (2.4)	1	0		2 (1.3)	2
Mild	0		0				0	
Moderate	1 (1.3)	1	1 (2.4)	1			2 (1.3)	2
Severe	0		0				0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Blood bilirubin increased	1 (1.3)	3	0		1 (2.6)	1	2 (1.3)	4
Mild	0				1 (2.6)	1	1 (0.6)	1
Moderate	1 (1.3)	3			0		1 (0.6)	3
Severe	0				0		0	
Blood cholesterol increased	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Blood potassium increased	2 (2.5)	2	0		0		2 (1.3)	2
Mild	1 (1.3)	1					1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	1 (1.3)	1					1 (0.6)	1
Severe	0						0	
Blood triglycerides increased	1 (1.3)	1	2 (4.9)	3	1 (2.6)	1	4 (2.5)	5
Mild	0		1 (2.4)	1	0		1 (0.6)	1
Moderate	1 (1.3)	1	2 (4.9)	2	1 (2.6)	1	4 (2.5)	4
Severe	0		0		0		0	
Carbon monoxide diffusing capacity decreased	0		0		1 (2.6)	1	1 (0.6)	1
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Forced expiratory volume decreased	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Gamma-glutamyltransferase increased	1 (1.3)	1	0		0		1 (0.6)	1
Mild	0						0	
Moderate	0						0	
Severe	1 (1.3)	1					1 (0.6)	1
Haemoglobin decreased	8 (10.0)	11	4 (9.8)	5	5 (12.8)	6	17 (10.6)	22
Mild	0		1 (2.4)	1	0		1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	5 (6.3)	6	2 (4.9)	2	4 (10.3)	4	11 (6.9)	12
Severe	5 (6.3)	5	2 (4.9)	2	2 (5.1)	2	9 (5.6)	9
Lymphocyte count increased	5 (6.3)	5	1 (2.4)	1	1 (2.6)	1	7 (4.4)	7
Mild	0		0		0		0	
Moderate	5 (6.3)	5	1 (2.4)	1	1 (2.6)	1	7 (4.4)	7
Severe	0		0		0		0	
Neutrophil count decreased	3 (3.8)	4	0		0		3 (1.9)	4
Mild	2 (2.5)	3					2 (1.3)	3
Moderate	1 (1.3)	1					1 (0.6)	1
Severe	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Vital capacity decreased	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Metabolism and nutrition disorders	2 (2.5)	3	0		1 (2.6)	1	3 (1.9)	4
Hyperglycaemia	0				1 (2.6)	1	1 (0.6)	1
Mild					0		0	
Moderate					1 (2.6)	1	1 (0.6)	1
Severe					0		0	
Hypertriglyceridaemia	2 (2.5)	3			0		2 (1.3)	3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild	0						0	
Moderate	2 (2.5)	2					2 (1.3)	2
Severe	1 (1.3)	1					1 (0.6)	1
Nervous system disorders	1 (1.3)	1	1 (2.4)	1	1 (2.6)	1	3 (1.9)	3
Headache	1 (1.3)	1	1 (2.4)	1	1 (2.6)	1	3 (1.9)	3
Mild	1 (1.3)	1	1 (2.4)	1	1 (2.6)	1	3 (1.9)	3
Moderate	0		0		0		0	
Severe	0		0		0		0	
Renal and urinary disorders	1 (1.3)	1	0		3 (7.7)	3	4 (2.5)	4
Dysuria	0				1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild					1 (2.6)	1	1 (0.6)	1
Moderate					0		0	
Severe					0		0	
Proteinuria	0				1 (2.6)	1	1 (0.6)	1
Mild					0		0	
Moderate					1 (2.6)	1	1 (0.6)	1
Severe					0		0	
Glycosuria	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Mild	0				0		0	
Moderate	0				1 (2.6)	1	1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	1 (1.3)	1			0		1 (0.6)	1
Reproductive system and breast disorders	1 (1.3)	1	0		0		1 (0.6)	1
Erectile dysfunction	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Respiratory, thoracic and mediastinal disorders	5 (6.3)	9	3 (7.3)	3	0		8 (5.0)	12
Cough	2 (2.5)	2	1 (2.4)	1			3 (1.9)	3
Mild	2 (2.5)	2	1 (2.4)	1			3 (1.9)	3
Moderate	0		0				0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0		0				0	
Nasal congestion	2 (2.5)	2	1 (2.4)	1			3 (1.9)	3
Mild	2 (2.5)	2	1 (2.4)	1			3 (1.9)	3
Moderate	0		0				0	
Severe	0		0				0	
Oropharyngeal pain	1 (1.3)	1	0				1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Pulmonary congestion	1 (1.3)	1	0				1 (0.6)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Respiratory disorder	1 (1.3)	1	0				1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Rhinitis allergic	0		1 (2.4)	1			1 (0.6)	1
Mild			1 (2.4)	1			1 (0.6)	1
Moderate			0				0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Severe			0				0	
Rhinorrhoea	1 (1.3)	1	0				1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Sinus congestion	1 (1.3)	1	0				1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Skin and subcutaneous tissue disorders	2 (2.5)	4	0		0		2 (1.3)	4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Acne	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Pruritus	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	
Rash	2 (2.5)	2					2 (1.3)	2
Mild	2 (2.5)	2					2 (1.3)	2

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-
Safety Population****Safety Time Period: Ambulatory Period**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0						0	
Severe	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

Appendix 15.3.6.1

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**Table 15.2.6.10 Summary of Adverse Events by System Organ Class and Preferred Term and Severity-Safety Population****Safety Time Period: Safety Follow-Up**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Adverse event	1 (1.3)	1	0		0		1 (0.6)	1
Mild	1 (1.3)	1	0		0		1 (0.6)	1
Moderate	0		0		0		0	
Severe	0		0		0		0	
Investigations	1 (1.3)	1	0		0		1 (0.6)	1
Aspartate aminotransferase increased	1 (1.3)	1					1 (0.6)	1
Mild	1 (1.3)	1					1 (0.6)	1
Moderate	0						0	
Severe	0						0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: IP = Investigational product(THSm2.2 or mCC)

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Adverse event	32 (47.8)	60	6 (60.0)	8	3 (100.0)	6
Mild	19 (28.4)	34	3 (30.0)	5	2 (66.7)	4
Moderate	13 (19.4)	18	3 (30.0)	3	2 (66.7)	2
Severe	8 (11.9)	8	0		0	
Eye disorders	2 (3.0)	2	0		0	
Conjunctivitis	1 (1.5)	1				
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					
Eye pruritus	1 (1.5)	1				
Mild	1 (1.5)	1				

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0					
Severe	0					
Gastrointestinal disorders	5 (7.5)	8	2 (20.0)	2	0	
Abdominal pain	1 (1.5)	1	0			
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					
Constipation	0		1 (10.0)	1		
Mild			1 (10.0)	1		
Moderate			0			
Severe			0			

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Diarrhoea	1 (1.5)	1	0			
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					
Dry mouth	1 (1.5)	1	0			
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					
Gingival bleeding	1 (1.5)	1	0			
Mild	1 (1.5)	1				
Moderate	0					

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0					
Gingival pain	1 (1.5)	1	0			
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					
Nausea	0		1 (10.0)	1		
Mild			1 (10.0)	1		
Moderate			0			
Severe			0			
Toothache	1 (1.5)	2	0			
Mild	1 (1.5)	1				

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	1 (1.5)	1				
Severe	0					
Vomiting	1 (1.5)	1	0			
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					
General disorders and administration site conditions	2 (3.0)	2	0		0	
Chest discomfort	1 (1.5)	1				
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Non-cardiac chest pain	1 (1.5)	1				
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					
Infections and infestations	4 (6.0)	4	0		0	
Upper respiratory tract infection	3 (4.5)	3				
Mild	3 (4.5)	3				
Moderate	0					
Severe	0					
Urinary tract infection	1 (1.5)	1				
Mild	1 (1.5)	1				

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0					
Severe	0					
Injury, poisoning and procedural complications	2 (3.0)	2	1 (10.0)	1	2 (66.7)	3
Excoriation	0		0		1 (33.3)	1
Mild					1 (33.3)	1
Moderate					0	
Severe					0	
Laceration	1 (1.5)	1	0		0	
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Ligament sprain	0		1 (10.0)	1	2 (66.7)	2
Mild			0		1 (33.3)	1
Moderate			1 (10.0)	1	1 (33.3)	1
Severe			0		0	
Thermal burn	1 (1.5)	1	0		0	
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					
Investigations	16 (23.9)	24	3 (30.0)	4	1 (33.3)	3
Alanine aminotransferase increased	1 (1.5)	1	0		0	
Mild	1 (1.5)	1				

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0					
Severe	0					
Aspartate aminotransferase increased	1 (1.5)	1	0		0	
Mild	0					
Moderate	1 (1.5)	1				
Severe	0					
Blood bilirubin increased	1 (1.5)	3	0		0	
Mild	0					
Moderate	1 (1.5)	3				
Severe	0					
Blood potassium increased	2 (3.0)	2	0		0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Mild	1 (1.5)	1				
Moderate	1 (1.5)	1				
Severe	0					
Blood triglycerides increased	0		1 (10.0)	1	0	
Mild			0			
Moderate			1 (10.0)	1		
Severe			0			
Forced expiratory volume decreased	0		0		1 (33.3)	1
Mild					1 (33.3)	1
Moderate					0	
Severe					0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Gamma-glutamyltransferase increased	1 (1.5)	1	0		0	
Mild	0					
Moderate	0					
Severe	1 (1.5)	1				
Haemoglobin decreased	7 (10.5)	10	1 (10.0)	1	0	
Mild	0		0			
Moderate	4 (6.0)	5	1 (10.0)	1		
Severe	5 (7.5)	5	0			
Lymphocyte count increased	4 (6.0)	4	0		1 (33.3)	1
Mild	0				0	
Moderate	4 (6.0)	4			1 (33.3)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0				0	
Neutrophil count decreased	2 (3.0)	2	1 (10.0)	2	0	
Mild	1 (1.5)	1	1 (10.0)	2		
Moderate	1 (1.5)	1	0			
Severe	0		0			
Vital capacity decreased	0		0		1 (33.3)	1
Mild					1 (33.3)	1
Moderate					0	
Severe					0	
Metabolism and nutrition disorders	2 (3.0)	3	0		0	
Hypertriglyceridaemia	2 (3.0)	3				

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Mild	0					
Moderate	2 (3.0)	2				
Severe	1 (1.5)	1				
Nervous system disorders	1 (1.5)	1	0		0	
Headache	1 (1.5)	1				
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					
Renal and urinary disorders	1 (1.5)	1	0		0	
Glycosuria	1 (1.5)	1				
Mild	0					

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0					
Severe	1 (1.5)	1				
Reproductive system and breast disorders	1 (1.5)	1	0		0	
Erectile dysfunction	1 (1.5)	1				
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					
Respiratory, thoracic and mediastinal disorders	5 (7.5)	9	0		0	
Cough	2 (3.0)	2				
Mild	2 (3.0)	2				
Moderate	0					

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0					
Nasal congestion	2 (3.0)	2				
Mild	2 (3.0)	2				
Moderate	0					
Severe	0					
Oropharyngeal pain	1 (1.5)	1				
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					
Pulmonary congestion	1 (1.5)	1				
Mild	1 (1.5)	1				

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Moderate	0					
Severe	0					
Respiratory disorder	1 (1.5)	1				
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					
Rhinorrhoea	1 (1.5)	1				
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					
Sinus congestion	1 (1.5)	1				

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					
Skin and subcutaneous tissue disorders	1 (1.5)	3	1 (10.0)	1	0	
Acne	1 (1.5)	1	0			
Mild	1 (1.5)	1				
Moderate	0					
Severe	0					
Pruritus	1 (1.5)	1	0			
Mild	1 (1.5)	1				
Moderate	0					

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events
Severe	0					
Rash	1 (1.5)	1	1 (10.0)	1		
Mild	1 (1.5)	1	1 (10.0)	1		
Moderate	0		0			
Severe	0		0			

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within mCC (N=41)	
	CC (N=40)	
	n(%)	Events
Adverse event	14 (35.0)	18
Mild	10 (25.0)	10
Moderate	6 (15.0)	6
Severe	2 (5.0)	2
Infections and infestations	3 (7.5)	3
Upper respiratory tract infection	3 (7.5)	3
Mild	3 (7.5)	3
Moderate	0	
Severe	0	
Injury, poisoning and procedural complications	1 (2.5)	1
Wound	1 (2.5)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within mCC (N=41)	
	CC (N=40)	
	n(%)	Events
Mild	1 (2.5)	1
Moderate	0	
Severe	0	
Investigations	8 (20.0)	10
Aspartate aminotransferase increased	1 (2.5)	1
Mild	0	
Moderate	1 (2.5)	1
Severe	0	
Blood triglycerides increased	2 (5.0)	3
Mild	1 (2.5)	1
Moderate	2 (5.0)	2

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within mCC (N=41)	
	CC (N=40)	
	n(%)	Events
Severe	0	
Haemoglobin decreased	4 (10.0)	5
Mild	1 (2.5)	1
Moderate	2 (5.0)	2
Severe	2 (5.0)	2
Lymphocyte count increased	1 (2.5)	1
Mild	0	
Moderate	1 (2.5)	1
Severe	0	
Nervous system disorders	1 (2.5)	1
Headache	1 (2.5)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within mCC (N=41)	
	CC (N=40)	
	n(%)	Events
Mild	1 (2.5)	1
Moderate	0	
Severe	0	
Respiratory, thoracic and mediastinal disorders	3 (7.5)	3
Cough	1 (2.5)	1
Mild	1 (2.5)	1
Moderate	0	
Severe	0	
Nasal congestion	1 (2.5)	1
Mild	1 (2.5)	1
Moderate	0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within mCC (N=41)	
	CC (N=40)	
	n(%)	Events
Severe	0	
Rhinitis allergic	1 (2.5)	1
Mild	1 (2.5)	1
Moderate	0	
Severe	0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within SA (N=39)					
	Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
	n(%)	Events	n(%)	Events	n(%)	Events
Adverse event	1 (16.7)	2	2 (50.0)	4	11 (45.8)	16
Mild	0		1 (25.0)	1	9 (37.5)	10
Moderate	1 (16.7)	1	2 (50.0)	3	4 (16.7)	5
Severe	1 (16.7)	1	0		1 (4.2)	1
Blood and lymphatic system disorders	0		0		1 (4.2)	1
Leukocytosis					1 (4.2)	1
Mild					1 (4.2)	1
Moderate					0	
Severe					0	
Ear and labyrinth disorders	0		0		1 (4.2)	1
Ear pain					1 (4.2)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within SA (N=39)					
	Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
	n(%)	Events	n(%)	Events	n(%)	Events
Mild					1 (4.2)	1
Moderate					0	
Severe					0	
General disorders and administration site conditions	0		0		1 (4.2)	1
Pyrexia					1 (4.2)	1
Mild					1 (4.2)	1
Moderate					0	
Severe					0	
Infections and infestations	0		0		1 (4.2)	1
Upper respiratory tract infection					1 (4.2)	1
Mild					1 (4.2)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within SA (N=39)					
	Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
	n(%)	Events	n(%)	Events	n(%)	Events
Moderate					0	
Severe					0	
Injury, poisoning and procedural complications	0		0		2 (8.3)	2
Arthropod bite					1 (4.2)	1
Mild					1 (4.2)	1
Moderate					0	
Severe					0	
Muscle strain					1 (4.2)	1
Mild					1 (4.2)	1
Moderate					0	
Severe					0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within SA (N=39)					
	Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
	n(%)	Events	n(%)	Events	n(%)	Events
Investigations	1 (16.7)	2	2 (50.0)	2	6 (25.0)	7
Blood bilirubin increased	0		0		1 (4.2)	1
Mild					1 (4.2)	1
Moderate					0	
Severe					0	
Blood cholesterol increased	0		0		1 (4.2)	1
Mild					1 (4.2)	1
Moderate					0	
Severe					0	
Blood triglycerides increased	0		0		1 (4.2)	1
Mild					0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within SA (N=39)					
	Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
	n(%)	Events	n(%)	Events	n(%)	Events
Moderate					1 (4.2)	1
Severe					0	
Carbon monoxide diffusing capacity decreased	0		0		1 (4.2)	1
Mild					1 (4.2)	1
Moderate					0	
Severe					0	
Haemoglobin decreased	1 (16.7)	2	1 (25.0)	1	3 (12.5)	3
Mild	0		0		0	
Moderate	1 (16.7)	1	1 (25.0)	1	2 (8.3)	2
Severe	1 (16.7)	1	0		1 (4.2)	1
Lymphocyte count increased	0		1 (25.0)	1	0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within SA (N=39)					
	Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
	n(%)	Events	n(%)	Events	n(%)	Events
Mild			0			
Moderate			1 (25.0)	1		
Severe			0			
Metabolism and nutrition disorders	0		0		1 (4.2)	1
Hyperglycaemia					1 (4.2)	1
Mild					0	
Moderate					1 (4.2)	1
Severe					0	
Nervous system disorders	0		0		1 (4.2)	1
Headache					1 (4.2)	1
Mild					1 (4.2)	1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within SA (N=39)					
	Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
	n(%)	Events	n(%)	Events	n(%)	Events
Moderate					0	
Severe					0	
Renal and urinary disorders	0		2 (50.0)	2	1 (4.2)	1
Dysuria			1 (25.0)	1	0	
Mild			1 (25.0)	1		
Moderate			0			
Severe			0			
Proteinuria			1 (25.0)	1	0	
Mild			0			
Moderate			1 (25.0)	1		
Severe			0			

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System Organ Class, Preferred Term and Severity - Safety Population**

	Within SA (N=39)					
	Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
	n(%)	Events	n(%)	Events	n(%)	Events
Glycosuria			0		1 (4.2)	1
Mild					0	
Moderate					1 (4.2)	1
Severe					0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: IP = Investigational product (THSm2.2 or mCC).

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.12 Summary of Serious Adverse Events by System Organ Class and Preferred Term-Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	0		0		0		1 (20.0)	2	1 (0.6)	2
Infections and infestations	0		0		0		1 (20.0)	1	1 (0.6)	1
Sinusitis							1 (20.0)	1	1 (0.6)	1
Metabolism and nutrition disorders	0		0		0		1 (20.0)	1	1 (0.6)	1
Diabetic ketoacidosis							1 (20.0)	1	1 (0.6)	1

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.12 Summary of Serious Adverse Events by System Organ Class and Preferred Term-Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events

No Serious adverse events by System Organ Class and Preferred Term were reported during this Period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol
Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.12 Summary of Serious Adverse Events by System Organ Class and Preferred Term-Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events

No Serious adverse events by System Organ Class and Preferred Term were reported during this Period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol
Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.12 Summary of Serious Adverse Events by System Organ Class and Preferred Term-Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events

No Serious adverse events by System Organ Class and Preferred Term were reported during this Period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol
Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.12 Summary of Serious Adverse Events by System Organ Class and Preferred Term-Safety Population****Safety Time Period: Safety Follow-Up**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events

No Serious adverse events by System Organ Class and Preferred Term were reported during this Period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol
Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.13 Summary of Adverse Events Leading to Study Discontinuation by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Pre-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Any adverse events	0		0		0		3 (60.0)	3	3 (1.8)	3
Injury, poisoning and procedural complications	0		0		0		1 (20.0)	1	1 (0.6)	1
Procedural complication							1 (20.0)	1	1 (0.6)	1
Investigations	0		0		0		1 (20.0)	1	1 (0.6)	1
Blood pressure increased							1 (20.0)	1	1 (0.6)	1
Nervous system disorders	0		0		0		1 (20.0)	1	1 (0.6)	1
Syncope							1 (20.0)	1	1 (0.6)	1

Note: Product Test refers to all subjects who tested the THS Product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.13 Summary of Adverse Events Leading to Study Discontinuation by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Post-Randomization**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events

No adverse events leading to Study Discontinuation were reported during this Period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol
Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.13 Summary of Adverse Events Leading to Study Discontinuation by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Confinement**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events

No adverse events leading to Study Discontinuation were reported during this Period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol
Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.13 Summary of Adverse Events Leading to Study Discontinuation by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Ambulatory**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events

No adverse events leading to Study Discontinuation were reported during this Period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol
Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.13 Summary of Adverse Events Leading to Study Discontinuation by System Organ Class and Preferred Term - Safety Population****Safety Time Period: Safety Follow-Up**

System Organ Class Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events

No adverse events leading to Study Discontinuation were reported during this Period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol
Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.14 Summary of Adverse Events Leading to Study Discontinuation by Product Use Category, System Organ Class and Preferred Term - Safety Population**

System Organ Class Preferred Term	Within THS 2.2 (N=80)					
	THS 2.2 (N=67)		Dual (N=10)		CC (N=3)	
	n(%)	Events	n(%)	Events	n(%)	Events

No adverse events leading to Study Discontinuation were reported during this Period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.14 Summary of Adverse Events Leading to Study Discontinuation by Product Use Category, System Organ Class and Preferred Term - Safety Population**

Within mCC (N=41)		CC (N=41)	
System Organ Class	Preferred Term	n(%) Events	
		n(%)	Events

No adverse events leading to Study Discontinuation were reported during this Period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.14 Summary of Adverse Events Leading to Study Discontinuation by Product Use Category, System Organ Class and Preferred Term - Safety Population**

System Organ Class Preferred Term	Within SA (N=39)					
	Abstinent (N=6)		Predominantly Abstinent (N=4)		Not Abstinent (N=24)	
	n(%)		n(%)		n(%)	
	Events		Events		Events	

No adverse events leading to Study Discontinuation were reported during this Period

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.15 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Pre-Randomization Period**

Device Events	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Device Events	0		1 (2.4)	1	0		0		1 (0.6)	1
Related to AE	0		0		0		0		0	
Not Related to AE	0		1 (2.4)	1	0		0		1 (0.6)	1
Device events by severity										
Major	0		1 (2.4)	1	0		0		1 (0.6)	1
Device Inoperable	0		1 (2.4)	1	0		0		1 (0.6)	1
Minor	0		0		0		0		0	

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.15 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Post-Randomization Period**

Device Events	THSm2.2 (N=80)	
	n (%)	Events
Device Events	55 (68.8)	149
Related to AE	0	
Not Related to AE	55 (68.8)	149
Device events by severity		
Major	55 (68.8)	149
Device Inoperable	47 (58.8)	94
No Information	16 (20.0)	25

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.15 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Post-Randomization Period**

Device Events	THSm2.2 (N=80)	
	n (%)	Events
Charging Issue	9 (11.3)	12
Device Handling Issue	3 (3.8)	4
Break	2 (2.5)	3
Device Difficult To Setup Or Prepare	3 (3.8)	3
Burn Of Device Or Device Component	1 (1.3)	1
Component Falling	1 (1.3)	1
Device Issue	1 (1.3)	1
Electrical Issue	1 (1.3)	1

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.15 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Post-Randomization Period**

Device Events	THSm2.2 (N=80)	
	n (%)	Events
Failure To Power-Up	1 (1.3)	1
Material Fragmentation	1 (1.3)	1
Mechanical Issue	1 (1.3)	1
Out-Of-Box Failure	1 (1.3)	1
Minor	0	

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.15 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Confinement Period**

Device Events	THSm2.2 (N=80)	
	n (%)	Events
Device Events	27 (33.8)	46
Related to AE	0	
Not Related to AE	27 (33.8)	46
Device events by severity		
Major	27 (33.8)	46
Device Inoperable	21 (26.3)	27
No Information	4 (5.0)	7

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.15 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Confinement Period**

Device Events	THSm2.2 (N=80)	
	n (%)	Events
Charging Issue	4 (5.0)	4
Break	2 (2.5)	3
Device Handling Issue	2 (2.5)	3
Device Difficult To Setup Or Prepare	1 (1.3)	1
Mechanical Issue	1 (1.3)	1
Minor	0	

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.15 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Ambulatory Period**

Device Events	THSm2.2 (N=80)	
	n (%)	Events
Device Events	46 (57.5)	103
Related to AE	0	
Not Related to AE	46 (57.5)	103
Device events by severity		
Major	46 (57.5)	103
Device Inoperable	38 (47.5)	67
No Information	13 (16.3)	18

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.15 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Ambulatory Period**

Device Events	THSm2.2 (N=80)	
	n (%)	Events
Charging Issue	6 (7.5)	8
Device Difficult To Setup Or Prepare	2 (2.5)	2
Burn Of Device Or Device Component	1 (1.3)	1
Component Falling	1 (1.3)	1
Device Handling Issue	1 (1.3)	1
Device Issue	1 (1.3)	1
Electrical Issue	1 (1.3)	1
Failure To Power-Up	1 (1.3)	1

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.15 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Ambulatory Period**

Device Events	THSm2.2 (N=80)	
	n (%)	Events
Material Fragmentation	1 (1.3)	1
Out-Of-Box Failure	1 (1.3)	1
Minor	0	

Note: THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Appendix 15.3.6.5

Study ID: ZRHM-REXA-08-US

Program: t_device.sas

Status: Final

21SEP15

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**Table 15.2.6.15 Summary of THS 2.2 Menthol Device Events - Safety Population****Safety Time Period: Safety Follow-up Period****Device Events**

No THS 2.2 events were reported in follow-up safety time period

Appendix 15.3.6.5

Study ID: ZRHM-REXA-08-US

Program: t_device.sas

Status: Final

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Alanine aminotransferase (IU/L)	Screening	n	80	41	39	4	164
		Mean (SD)	20.2 (11.74)	19.9 (10.42)	19.2 (8.51)	24.8 (10.15)	20.0 (10.63)
		Median	18.5	16.0	18.0	22.5	18.0
		Min, Max	4, 79	9, 51	7, 50	15, 39	4, 79
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	76 (95.0)	39 (95.1)	38 (97.4)	3 (60.0)	156 (94.5)
		High value - n (%)	4 (5.0)	2 (4.9)	1 (2.6)	1 (20.0)	8 (4.8)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	2 (4.9)	1 (2.6)	1 (20.0)	8 (4.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Alanine aminotransferase (IU/L)	Screening	ALT increased					
		Grade 0 - n (%)	76 (95.0)	39 (95.1)	38 (97.4)	3 (60.0)	156 (94.5)
		Grade 1 - n (%)	4 (5.0)	2 (4.9)	1 (2.6)	1 (20.0)	8 (4.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Alanine aminotransferase (IU/L)	Day 0	n	80	41	39	3	163
		Mean (SD)	18.6 (11.28)	17.0 (6.57)	18.3 (8.75)	NC	18.4 (9.98)
		Median	17.0	16.0	16.0	NC	16.0
		Min, Max	6, 88	7, 36	9, 59	NC	6, 88
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	77 (96.3)	40 (97.6)	38 (97.4)	2 (40.0)	157 (95.2)
		High value - n (%)	3 (3.8)	1 (2.4)	1 (2.6)	1 (20.0)	6 (3.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	1 (2.4)	1 (2.6)	1 (20.0)	6 (3.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Alanine aminotransferase (IU/L)	Day 0	ALT increased					
		Grade 0 - n (%)	77 (96.3)	40 (97.6)	38 (97.4)	2 (40.0)	157 (95.2)
		Grade 1 - n (%)	3 (3.8)	1 (2.4)	1 (2.6)	1 (20.0)	6 (3.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Aspartate aminotransferase (IU/L)	Screening	n	80	41	39	4	164
		Mean (SD)	20.0 (9.41)	20.3 (5.61)	19.4 (4.48)	22.0 (4.17)	20.0 (7.47)
		Median	18.0	19.0	19.0	22.0	19.0
		Min, Max	10, 84	14, 34	11, 29	17, 27	10, 84
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	79 (98.8)	41 (100)	39 (100)	4 (80.0)	163 (98.8)
		High value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Aspartate aminotransferase (IU/L)	Screening	AST increased					
		Grade 0 - n (%)	79 (98.8)	41 (100)	39 (100)	4 (80.0)	163 (98.8)
		Grade 1 - n (%)	1 (1.3)	0	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Aspartate aminotransferase (IU/L)	Day 0	n	80	41	39	3	163
		Mean (SD)	18.8 (7.05)	17.8 (4.17)	19.4 (4.93)	NC	18.7 (5.90)
		Median	17.5	17.0	19.0	NC	18.0
		Min, Max	10, 60	10, 27	11, 34	NC	10, 60
		Low value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Normal value - n (%)	77 (96.3)	41 (100)	39 (100)	3 (60.0)	160 (97.0)
		High value - n (%)	2 (2.5)	0	0	0	2 (1.2)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	0	0	0	3 (1.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Aspartate aminotransferase (IU/L)	Day 0	AST increased					
		Grade 0 - n (%)	78 (97.5)	41 (100)	39 (100)	3 (60.0)	161 (97.6)
		Grade 1 - n (%)	2 (2.5)	0	0	0	2 (1.2)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Bilirubin (mg/dL)	Screening	n	80	41	39	4	164
		Mean (SD)	0.45 (0.277)	0.41 (0.168)	0.46 (0.189)	0.50 (0.142)	0.45 (0.231)
		Median	0.40	0.40	0.50	0.55	0.40
		Min, Max	0.1, 1.4	0.2, 0.8	0.1, 0.9	0.3, 0.6	0.1, 1.4
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	78 (97.5)	41 (100)	39 (100)	4 (80.0)	162 (98.2)
		High value - n (%)	2 (2.5)	0	0	0	2 (1.2)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	0	0	0	2 (1.2)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Bilirubin (mg/dL)	Screening	Blood bilirubin increased					
		Grade 0 - n (%)	78 (97.5)	41 (100)	39 (100)	4 (80.0)	162 (98.2)
		Grade 1 - n (%)	2 (2.5)	0	0	0	2 (1.2)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US

Program: t_labchem.sas

Status: Final

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Bilirubin (mg/dL)	Day 0	n	80	41	39	3	163
		BLOQ, n (%)	1 (1.3)	0	0	0	1 (0.6)
		Mean (SD)	0.46 (0.173)	0.48 (0.205)	0.47 (0.208)	NC	0.47 (0.212)
		Median	0.40	0.50	0.40	NC	0.40
		Min, Max	0.1, 1.0	0.2, 1.2	0.2, 1.0	NC	0.1, 1.7
		Low value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Normal value - n (%)	79 (98.8)	41 (100)	39 (100)	2 (40.0)	161 (97.6)
		High value - n (%)	0	0	0	1 (20.0)	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (20.0)	2 (1.2)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Bilirubin (mg/dL)	Day 0	Blood bilirubin increased					
		Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	2 (40.0)	162 (98.2)
		Grade 1 - n (%)	0	0	0	1 (20.0)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US

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Status: Final

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Direct bilirubin (mg/dL) [0-0.4]	Screening	n	80	41	39	4	164
		BLOQ, n (%)	0	0	1 (2.6)	0	1 (0.6)
		Mean (SD)	0.130 (0.0538)	0.124 (0.0489)	0.128 (0.0504)	0.125 (0.0500)	0.128 (0.0513)
		Median	0.100	0.100	0.100	0.100	0.100
		Min, Max	0.10, 0.30	0.10, 0.30	0.01, 0.20	0.10, 0.20	0.01, 0.30
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	4 (80.0)	164 (99.4)
		High value - n (%)	0	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Direct bilirubin (mg/dL) [0-0.4]	Day 0	n	79	41	39	3	162
		BLOQ, n (%)	33 (41.8)	14 (34.1)	17 (43.6)	1 (33.3)	65 (40.1)
		Mean (SD)	0.092 (0.0477)	0.107 (0.0577)	0.094 (0.0516)	NC	0.097 (0.0536)
		Median	0.100	0.100	0.100	NC	0.100
		Min, Max	0.05, 0.20	0.05, 0.20	0.05, 0.20	NC	0.05, 0.30
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	79 (98.8)	41 (100)	39 (100)	3 (60.0)	162 (98.2)
		High value - n (%)	0	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Alkaline phosphatase (IU/L)	Screening	n	80	41	39	4	164
		Mean (SD)	69.3 (20.62)	68.5 (22.09)	71.0 (18.71)	78.8 (12.37)	69.7 (20.33)
		Median	66.5	66.0	70.0	80.0	67.0
		Min, Max	36, 135	28, 123	42, 130	63, 92	28, 135
		Low value - n (%)	2 (2.5)	3 (7.3)	0	0	5 (3.0)
		Normal value - n (%)	76 (95.0)	36 (87.8)	37 (94.9)	4 (80.0)	153 (92.7)
		High value - n (%)	2 (2.5)	2 (4.9)	2 (5.1)	0	6 (3.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	5 (12.2)	2 (5.1)	0	11 (6.7)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Alkaline phosphatase (IU/L)	Screening	Alkaline phosphatase increased					
		Grade 0 - n (%)	78 (97.5)	39 (95.1)	37 (94.9)	4 (80.0)	158 (95.8)
		Grade 1 - n (%)	2 (2.5)	2 (4.9)	2 (5.1)	0	6 (3.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Alkaline phosphatase (IU/L)	Day 0	n	80	41	39	3	163
		Mean (SD)	68.1 (20.71)	67.0 (20.13)	69.6 (17.12)	NC	68.3 (19.53)
		Median	65.0	65.0	70.0	NC	66.0
		Min, Max	33, 136	36, 116	43, 131	NC	33, 136
		Low value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Normal value - n (%)	78 (97.5)	41 (100)	38 (97.4)	3 (60.0)	160 (97.0)
		High value - n (%)	1 (1.3)	0	1 (2.6)	0	2 (1.2)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	0	1 (2.6)	0	3 (1.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Alkaline phosphatase (IU/L)	Day 0	Alkaline phosphatase increased					
		Grade 0 - n (%)	79 (98.8)	41 (100)	38 (97.4)	3 (60.0)	161 (97.6)
		Grade 1 - n (%)	1 (1.3)	0	1 (2.6)	0	2 (1.2)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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Status: Final

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Gamma glutamyl transferase (IU/L)	Screening	n	80	41	39	4	164
		Mean (SD)	25.2 (23.76)	22.1 (18.73)	23.4 (11.80)	18.5 (9.75)	23.9 (19.91)
		Median	19.0	17.0	21.0	16.5	18.0
		Min, Max	6, 187	7, 120	9, 60	9, 32	6, 187
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	77 (96.3)	40 (97.6)	39 (100)	4 (80.0)	160 (97.0)
		High value - n (%)	3 (3.8)	1 (2.4)	0	0	4 (2.4)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	1 (2.4)	0	0	4 (2.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Gamma glutamyl transferase (IU/L)	Screening	GGT increased					
		Grade 0 - n (%)	77 (96.3)	40 (97.6)	39 (100)	4 (80.0)	160 (97.0)
		Grade 1 - n (%)	2 (2.5)	1 (2.4)	0	0	3 (1.8)
		Grade 2 - n (%)	1 (1.3)	0	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Gamma glutamyl transferase (IU/L)	Day 0	n	80	41	39	3	163
		Mean (SD)	24.0 (17.68)	20.7 (14.71)	23.3 (10.87)	NC	22.9 (15.39)
		Median	19.0	16.0	21.0	NC	18.0
		Min, Max	5, 126	7, 89	11, 55	NC	5, 126
		Low value - n (%)	2 (2.5)	0	0	0	2 (1.2)
		Normal value - n (%)	74 (92.5)	40 (97.6)	39 (100)	3 (60.0)	156 (94.5)
		High value - n (%)	4 (5.0)	1 (2.4)	0	0	5 (3.0)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	6 (7.5)	1 (2.4)	0	0	7 (4.2)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Gamma glutamyl transferase (IU/L)	Day 0	GGT increased					
		Grade 0 - n (%)	76 (95.0)	40 (97.6)	39 (100)	3 (60.0)	158 (95.8)
		Grade 1 - n (%)	3 (3.8)	1 (2.4)	0	0	4 (2.4)
		Grade 2 - n (%)	1 (1.3)	0	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Glucose (mg/dL)	Screening	n	79	41	39	4	163
		Mean (SD)	86.4 (7.66)	85.7 (6.11)	86.5 (10.35)	94.5 (10.38)	86.4 (8.15)
		Median	87.0	86.0	85.0	90.0	86.0
		Min, Max	66, 102	70, 98	73, 127	88, 110	66, 127
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	78 (97.5)	41 (100)	37 (94.9)	3 (60.0)	159 (96.4)
		High value - n (%)	1 (1.3)	0	2 (5.1)	1 (20.0)	4 (2.4)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	2 (5.1)	1 (20.0)	4 (2.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Glucose (mg/dL)	Screening	Hyperglycemia					
		Grade 0 - n (%)	78 (97.5)	41 (100)	37 (94.9)	3 (60.0)	159 (96.4)
		Grade 1 - n (%)	1 (1.3)	0	2 (5.1)	1 (20.0)	4 (2.4)
		Hypoglycemia					
		Grade 0 - n (%)	79 (98.8)	41 (100)	39 (100)	4 (80.0)	163 (98.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Glucose (mg/dL)	Day 0	n	55	28	31	3	117
		Mean (SD)	95.3 (7.57)	94.9 (8.50)	95.1 (8.82)	NC	95.3 (8.05)
		Median	95.0	94.0	94.0	NC	94.0
		Min, Max	83, 118	83, 116	81, 113	NC	81, 118
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	43 (53.8)	22 (53.7)	23 (59.0)	2 (40.0)	90 (54.5)
		High value - n (%)	12 (15.0)	6 (14.6)	8 (20.5)	1 (20.0)	27 (16.4)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	12 (15.0)	6 (14.6)	8 (20.5)	1 (20.0)	27 (16.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Glucose (mg/dL)	Day 0	Hyperglycemia					
		Grade 0 - n (%)	43 (53.8)	22 (53.7)	23 (59.0)	2 (40.0)	90 (54.5)
		Grade 1 - n (%)	12 (15.0)	6 (14.6)	8 (20.5)	1 (20.0)	27 (16.4)
		Hypoglycemia					
		Grade 0 - n (%)	55 (68.8)	28 (68.3)	31 (79.5)	3 (60.0)	117 (70.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Creatinine (mg/dL)	Screening	n	80	41	39	4	164
		Mean (SD)	0.820 (0.1584)	0.837 (0.1782)	0.826 (0.1627)	0.768 (0.1103)	0.825 (0.1627)
		Median	0.805	0.800	0.790	0.760	0.800
		Min, Max	0.51, 1.15	0.56, 1.32	0.59, 1.16	0.66, 0.89	0.51, 1.32
		Low value - n (%)	7 (8.8)	4 (9.8)	4 (10.3)	0	15 (9.1)
		Normal value - n (%)	73 (91.3)	36 (87.8)	34 (87.2)	4 (80.0)	147 (89.1)
		High value - n (%)	0	1 (2.4)	1 (2.6)	0	2 (1.2)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	7 (8.8)	5 (12.2)	5 (12.8)	0	17 (10.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Creatinine (mg/dL)	Screening	Creatinine increased					
		Grade 0 - n (%)	80 (100)	40 (97.6)	38 (97.4)	4 (80.0)	162 (98.2)
		Grade 1 - n (%)	0	1 (2.4)	1 (2.6)	0	2 (1.2)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Creatinine (mg/dL) Day 0	n		80	41	39	3	163
	Mean (SD)		0.930 (0.1634)	0.971 (0.2695)	0.926 (0.1698)	NC	0.937 (0.1963)
	Median		0.900	0.900	0.900	NC	0.900
	Min, Max		0.60, 1.30	0.70, 2.30	0.60, 1.30	NC	0.60, 2.30
	Low value - n (%)		0	0	0	0	0
	Normal value - n (%)		79 (98.8)	39 (95.1)	38 (97.4)	3 (60.0)	159 (96.4)
	High value - n (%)		1 (1.3)	2 (4.9)	1 (2.6)	0	4 (2.4)
	Abnormal CS - n (%)		0	0	0	0	0
	Abnormal NCS - n (%)		1 (1.3)	2 (4.9)	1 (2.6)	0	4 (2.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Creatinine (mg/dL) Day 0		Creatinine increased					
		Grade 0 - n (%)	79 (98.8)	39 (95.1)	38 (97.4)	3 (60.0)	159 (96.4)
		Grade 1 - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	0	3 (1.8)
		Grade 2 - n (%)	0	1 (2.4)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Protein (g/dL)	Screening	n	80	41	39	4	164
		Mean (SD)	7.16 (0.427)	7.22 (0.555)	7.17 (0.444)	7.70 (0.698)	7.19 (0.476)
		Median	7.20	7.30	7.20	7.55	7.20
		Min, Max	6.2, 8.3	5.6, 8.6	6.1, 8.4	7.1, 8.6	5.6, 8.6
		Low value - n (%)	0	1 (2.4)	0	0	1 (0.6)
		Normal value - n (%)	80 (100)	38 (92.7)	39 (100)	3 (60.0)	160 (97.0)
		High value - n (%)	0	2 (4.9)	0	1 (20.0)	3 (1.8)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	3 (7.3)	0	1 (20.0)	4 (2.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Protein (g/dL)	Screening	Hypoproteinemia					
		Grade 0 - n (%)	80 (100)	40 (97.6)	39 (100)	4 (80.0)	163 (98.8)
		Grade 1 - n (%)	0	1 (2.4)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Protein (g/dL)	Day 0	n	80	41	39	3	163
		Mean (SD)	7.12 (0.430)	7.21 (0.504)	7.19 (0.477)	NC	7.17 (0.462)
		Median	7.00	7.20	7.30	NC	7.10
		Min, Max	6.3, 8.4	6.4, 9.3	6.1, 8.1	NC	6.1, 9.3
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	80 (100)	40 (97.6)	39 (100)	3 (60.0)	162 (98.2)
		High value - n (%)	0	1 (2.4)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Protein (g/dL)	Day 0	Hypoproteinemia Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	3 (60.0)	163 (98.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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Status: Final

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Blood urea nitrogen (mg/dL)	Screening	n	80	41	39	4	164
		Mean (SD)	10.7 (3.31)	10.8 (2.88)	11.1 (2.94)	11.5 (2.65)	10.8 (3.09)
		Median	11.0	11.0	11.0	11.0	11.0
		Min, Max	4, 22	3, 17	6, 19	9, 15	3, 22
		Low value - n (%)	2 (2.5)	1 (2.4)	0	0	3 (1.8)
		Normal value - n (%)	76 (95.0)	40 (97.6)	39 (100)	4 (80.0)	159 (96.4)
		High value - n (%)	2 (2.5)	0	0	0	2 (1.2)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	1 (2.4)	0	0	5 (3.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Blood urea nitrogen (mg/dL)	Screening	Blood Urea Nitrogen					
		Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	4 (80.0)	164 (99.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Blood urea nitrogen (mg/dL)	Day 0	n	80	41	39	3	163
		Mean (SD)	14.2 (2.89)	14.2 (2.59)	14.0 (2.79)	NC	14.2 (2.79)
		Median	14.0	14.0	14.0	NC	14.0
		Min, Max	8, 22	9, 20	6, 19	NC	6, 22
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	3 (60.0)	163 (98.8)
		High value - n (%)	0	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Blood urea nitrogen (mg/dL)	Day 0	Blood Urea Nitrogen					
		Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	3 (60.0)	163 (98.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Triglycerides (mg/dL)	Screening	n	80	41	39	4	164
		Mean (SD)	101.9 (56.77)	97.9 (50.36)	101.8 (47.69)	147.8 (62.91)	102.0 (53.32)
		Median	82.0	87.0	91.0	156.5	85.0
		Min, Max	43, 300	45, 314	38, 219	63, 215	38, 314
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	65 (81.3)	38 (92.7)	32 (82.1)	1 (20.0)	136 (82.4)
		High value - n (%)	15 (18.8)	3 (7.3)	7 (17.9)	3 (60.0)	28 (17.0)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	15 (18.8)	3 (7.3)	7 (17.9)	3 (60.0)	28 (17.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Triglycerides (mg/dL)	Screening	Hypertriglyceridemia					
		Grade 0 - n (%)	65 (81.3)	38 (92.7)	32 (82.1)	1 (20.0)	136 (82.4)
		Grade 1 - n (%)	15 (18.8)	2 (4.9)	7 (17.9)	3 (60.0)	27 (16.4)
		Grade 2 - n (%)	0	1 (2.4)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Triglycerides (mg/dL)	Day 0	n	80	41	39	3	163
		Mean (SD)	135.8 (69.59)	129.6 (45.39)	124.6 (43.89)	NC	132.2 (58.39)
		Median	121.0	118.0	114.0	NC	118.0
		Min, Max	54, 438	68, 248	68, 238	NC	54, 438
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	75 (93.8)	37 (90.2)	38 (97.4)	3 (60.0)	153 (92.7)
		High value - n (%)	5 (6.3)	4 (9.8)	1 (2.6)	0	10 (6.1)
		Abnormal CS - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Abnormal NCS - n (%)	4 (5.0)	4 (9.8)	1 (2.6)	0	9 (5.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Triglycerides (mg/dL)	Day 0	Hypertriglyceridemia					
		Grade 0 - n (%)	56 (70.0)	26 (63.4)	29 (74.4)	1 (20.0)	112 (67.9)
		Grade 1 - n (%)	20 (25.0)	15 (36.6)	10 (25.6)	2 (40.0)	47 (28.5)
		Grade 2 - n (%)	4 (5.0)	0	0	0	4 (2.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Cholesterol (mg/dL)	Screening	n	80	41	39	4	164
		Mean (SD)	182.4 (38.26)	189.4 (32.70)	187.5 (39.35)	180.0 (17.11)	185.3 (36.72)
		Median	181.0	186.0	187.0	183.5	182.0
		Min, Max	93, 271	119, 261	127, 262	158, 195	93, 271
		Low value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Normal value - n (%)	52 (65.0)	25 (61.0)	24 (61.5)	4 (80.0)	105 (63.6)
		High value - n (%)	27 (33.8)	16 (39.0)	15 (38.5)	0	58 (35.2)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	28 (35.0)	16 (39.0)	15 (38.5)	0	59 (35.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Cholesterol (mg/dL)	Screening	Cholesterol high					
		Grade 0 - n (%)	53 (66.3)	25 (61.0)	24 (61.5)	4 (80.0)	106 (64.2)
		Grade 1 - n (%)	27 (33.8)	16 (39.0)	15 (38.5)	0	58 (35.2)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Cholesterol (mg/dL)	Day 0	n	80	41	39	3	163
		Mean (SD)	189.9 (39.47)	192.9 (36.05)	193.8 (37.37)	NC	191.3 (37.69)
		Median	189.0	194.0	188.0	NC	189.0
		Min, Max	90, 304	129, 273	139, 266	NC	90, 304
		Low value - n (%)	11 (13.8)	3 (7.3)	4 (10.3)	0	18 (10.9)
		Normal value - n (%)	65 (81.3)	36 (87.8)	35 (89.7)	3 (60.0)	139 (84.2)
		High value - n (%)	4 (5.0)	2 (4.9)	0	0	6 (3.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	15 (18.8)	5 (12.2)	4 (10.3)	0	24 (14.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Cholesterol (mg/dL)	Day 0	Cholesterol high					
		Grade 0 - n (%)	76 (95.0)	39 (95.1)	39 (100)	3 (60.0)	157 (95.2)
		Grade 1 - n (%)	3 (3.8)	2 (4.9)	0	0	5 (3.0)
		Grade 2 - n (%)	1 (1.3)	0	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Albumin (g/L)	Screening	n	80	41	39	4	164
		Mean (SD)	44.9 (3.13)	45.8 (3.70)	45.2 (2.81)	46.8 (2.22)	45.3 (3.20)
		Median	45.0	46.0	46.0	46.0	46.0
		Min, Max	39, 52	37, 53	39, 51	45, 50	37, 53
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	4 (80.0)	164 (99.4)
		High value - n (%)	0	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Albumin (g/L)	Screening	Hypoalbuminemia Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	4 (80.0)	164 (99.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Albumin (g/L)	Day 0	n	80	41	39	3	163
		Mean (SD)	41.0 (3.24)	41.5 (2.60)	41.0 (3.73)	NC	41.1 (3.21)
		Median	41.0	41.0	41.0	NC	41.0
		Min, Max	34, 50	36, 47	34, 48	NC	34, 50
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	79 (98.8)	41 (100)	39 (100)	3 (60.0)	162 (98.2)
		High value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Albumin (g/L)	Day 0	Hypoalbuminemia Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	3 (60.0)	163 (98.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Sodium (mmol/L)	Screening	n	80	41	39	4	164
		Mean (SD)	139.2 (2.60)	139.6 (2.44)	139.5 (2.31)	140.0 (2.17)	139.4 (2.47)
		Median	139.0	140.0	140.0	139.5	139.0
		Min, Max	128, 145	132, 145	132, 144	138, 143	128, 145
		Low value - n (%)	2 (2.5)	1 (2.4)	1 (2.6)	0	4 (2.4)
		Normal value - n (%)	77 (96.3)	39 (95.1)	38 (97.4)	4 (80.0)	158 (95.8)
		High value - n (%)	1 (1.3)	1 (2.4)	0	0	2 (1.2)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	2 (4.9)	1 (2.6)	0	6 (3.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Sodium (mmol/L)	Screening	Hypernatremia					
		Grade 0 - n (%)	79 (98.8)	40 (97.6)	39 (100)	4 (80.0)	162 (98.2)
		Grade 1 - n (%)	1 (1.3)	1 (2.4)	0	0	2 (1.2)
		Hyponatremia					
		Grade 0 - n (%)	78 (97.5)	40 (97.6)	38 (97.4)	4 (80.0)	160 (97.0)
		Grade 1 - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	0	3 (1.8)
		Grade 3 - n (%)	1 (1.3)	0	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Sodium (mmol/L)	Day 0	n	80	41	39	3	163
		Mean (SD)	140.3 (1.87)	140.3 (2.30)	140.2 (1.80)	NC	140.3 (1.95)
		Median	140.0	140.0	140.0	NC	140.0
		Min, Max	136, 147	133, 146	137, 144	NC	133, 147
		Low value - n (%)	0	1 (2.4)	0	0	1 (0.6)
		Normal value - n (%)	80 (100)	40 (97.6)	39 (100)	3 (60.0)	162 (98.2)
		High value - n (%)	0	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Sodium (mmol/L)	Day 0	Hypernatremia					
		Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	3 (60.0)	163 (98.8)
		Hyponatremia					
		Grade 0 - n (%)	80 (100)	40 (97.6)	39 (100)	3 (60.0)	162 (98.2)
		Grade 1 - n (%)	0	1 (2.4)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Potassium (mmol/L)	Screening	n	80	41	39	4	164
		Mean (SD)	4.33 (0.413)	4.41 (0.463)	4.28 (0.388)	4.58 (0.768)	4.35 (0.430)
		Median	4.20	4.30	4.30	4.30	4.30
		Min, Max	3.3, 5.4	3.8, 5.9	3.7, 5.3	4.0, 5.7	3.3, 5.9
		Low value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Normal value - n (%)	78 (97.5)	39 (95.1)	38 (97.4)	3 (60.0)	158 (95.8)
		High value - n (%)	1 (1.3)	2 (4.9)	1 (2.6)	1 (20.0)	5 (3.0)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	2 (4.9)	1 (2.6)	1 (20.0)	6 (3.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Potassium (mmol/L)	Screening	Hyperkalemia					
		Grade 0 - n (%)	79 (98.8)	39 (95.1)	38 (97.4)	3 (60.0)	159 (96.4)
		Grade 1 - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	0	3 (1.8)
		Grade 2 - n (%)	0	1 (2.4)	0	1 (20.0)	2 (1.2)
		Hypokalemia					
		Grade 0 - n (%)	79 (98.8)	41 (100)	39 (100)	4 (80.0)	163 (98.8)
		Grade 1 - n (%)	1 (1.3)	0	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Potassium (mmol/L)	Day 0	n	80	41	39	3	163
		Mean (SD)	4.28 (0.333)	4.27 (0.345)	4.14 (0.333)	NC	4.24 (0.341)
		Median	4.30	4.30	4.20	NC	4.20
		Min, Max	3.6, 5.3	3.5, 5.0	3.4, 4.9	NC	3.4, 5.3
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	3 (60.0)	163 (98.8)
		High value - n (%)	0	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Potassium (mmol/L)	Day 0	Hyperkalemia					
		Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	3 (60.0)	163 (98.8)
		Hypokalemia					
		Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	3 (60.0)	163 (98.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Ldl cholesterol (mg/dL)	Day 0	n	80	41	39	3	163
		Mean (SD)	116.8 (35.33)	120.8 (33.00)	124.8 (35.74)	NC	119.6 (34.60)
		Median	113.5	115.0	117.0	NC	114.0
		Min, Max	30, 204	62, 199	71, 197	NC	30, 204
		Low value - n (%)	11 (13.8)	1 (2.4)	2 (5.1)	0	14 (8.5)
		Normal value - n (%)	66 (82.5)	37 (90.2)	36 (92.3)	3 (60.0)	142 (86.1)
		High value - n (%)	3 (3.8)	3 (7.3)	1 (2.6)	0	7 (4.2)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Baseline	n	80	41	39	160
		Mean (SD)	18.6 (11.28)	17.0 (6.57)	18.3 (8.75)	18.1 (9.63)
		Median	17.0	16.0	16.0	16.0
		Min, Max	6, 88	7, 36	9, 59	6, 88
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	77 (96.3)	40 (97.6)	38 (97.4)	155 (96.9)
		High value - n (%)	3 (3.8)	1 (2.4)	1 (2.6)	5 (3.1)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	1 (2.4)	1 (2.6)	5 (3.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Baseline	ALT increased				
		Grade 0 - n (%)	77 (96.3)	40 (97.6)	38 (97.4)	155 (96.9)
		Grade 1 - n (%)	3 (3.8)	1 (2.4)	1 (2.6)	5 (3.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	20.5 (13.13)	17.5 (7.62)	22.5 (9.99)	20.2 (11.32)
		Median	17.0	16.0	19.0	17.0
		Min, Max	6, 105	8, 42	11, 48	6, 105
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	77 (96.3)	40 (97.6)	32 (82.1)	149 (93.1)
		High value - n (%)	3 (3.8)	0	3 (7.7)	6 (3.8)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	0	3 (7.7)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Day 6/Discharge Confinement	ALT increased				
		Grade 0 - n (%)	77 (96.3)	40 (97.6)	32 (82.1)	149 (93.1)
		Grade 1 - n (%)	3 (3.8)	0	3 (7.7)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	1.9 (10.82)	0.7 (7.06)	4.0 (10.59)	2.0 (9.94)
		Median	1.0	0.5	3.0	1.0
		Min, Max	-47, 59	-14, 25	-20, 33	-47, 59

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Normal - n (%)	76 (95.0)	39 (95.1)	32 (82.1)	147 (91.9)
		Normal to High, NCS - n (%)	1 (1.3)	0	2 (5.1)	3 (1.9)
		High, NCS to Normal - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		High, NCS to High, NCS - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	ALT increased				
		0 to 0 - n (%)	76 (95.0)	39 (95.1)	32 (82.1)	147 (91.9)
		0 to 1 - n (%)	1 (1.3)	0	2 (5.1)	3 (1.9)
		1 to 0 - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		1 to 1 - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Day 30	n	77	39	33	149
		Mean (SD)	19.0 (12.05)	17.4 (11.22)	17.6 (6.70)	18.3 (10.83)
		Median	15.0	13.0	17.0	15.0
		Min, Max	5, 88	8, 58	7, 38	5, 88
		Low value - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)
		High value - n (%)	2 (2.5)	3 (7.3)	0	5 (3.1)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	3 (7.3)	0	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Day 30	ALT increased				
		Grade 0 - n (%)	75 (93.8)	36 (87.8)	33 (84.6)	144 (90.0)
		Grade 1 - n (%)	2 (2.5)	3 (7.3)	0	5 (3.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Change from Baseline to Day 30	n	77	39	33	149
		Mean (SD)	0.1 (11.82)	0.6 (8.90)	-0.6 (8.43)	0.1 (10.38)
		Median	0.0	-1.0	0.0	0.0
		Min, Max	-66, 44	-19, 29	-30, 23	-66, 44

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Shift in Normality from Baseline to Day 30	Normal to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	72 (90.0)	36 (87.8)	32 (82.1)	140 (87.5)
		Normal to High, NCS - n (%)	1 (1.3)	2 (4.9)	0	3 (1.9)
		High, NCS to Normal - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)
		High, NCS to High, NCS - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Shift in Toxicity from Baseline to Day 30	ALT increased				
		0 to 0 - n (%)	73 (91.3)	36 (87.8)	32 (82.1)	141 (88.1)
		0 to 1 - n (%)	1 (1.3)	2 (4.9)	0	3 (1.9)
		1 to 0 - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)
		1 to 1 - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Day 60	n	74	37	31	142
		Mean (SD)	20.0 (14.07)	14.5 (5.42)	19.0 (14.43)	18.3 (12.63)
		Median	16.0	13.0	14.0	15.0
		Min, Max	6, 97	7, 29	7, 80	6, 97
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	69 (86.3)	37 (90.2)	30 (76.9)	136 (85.0)
		High value - n (%)	5 (6.3)	0	1 (2.6)	6 (3.8)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	5 (6.3)	0	1 (2.6)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Day 60	ALT increased				
		Grade 0 - n (%)	69 (86.3)	37 (90.2)	30 (76.9)	136 (85.0)
		Grade 1 - n (%)	5 (6.3)	0	1 (2.6)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	1.3 (13.27)	-2.5 (5.64)	0.9 (13.57)	0.2 (11.88)
		Median	1.0	-2.0	-1.0	-1.0
		Min, Max	-37, 70	-16, 10	-19, 65	-37, 70

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	67 (83.8)	36 (87.8)	29 (74.4)	132 (82.5)
		Normal to High, NCS - n (%)	4 (5.0)	0	1 (2.6)	5 (3.1)
		High, NCS to Normal - n (%)	2 (2.5)	1 (2.4)	1 (2.6)	4 (2.5)
		High, NCS to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Shift in Toxicity from Baseline to Day 60	ALT increased				
		0 to 0 - n (%)	67 (83.8)	36 (87.8)	29 (74.4)	132 (82.5)
		0 to 1 - n (%)	4 (5.0)	0	1 (2.6)	5 (3.1)
		1 to 0 - n (%)	2 (2.5)	1 (2.4)	1 (2.6)	4 (2.5)
		1 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Day 91/Discharge n Ambulatory		74	36	33	143
		Mean (SD)	20.8 (16.53)	17.6 (10.61)	19.5 (11.05)	19.7 (14.06)
		Median	17.0	15.0	17.0	16.0
		Min, Max	5, 110	8, 67	8, 68	5, 110
		Low value - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value - n (%)	70 (87.5)	34 (82.9)	32 (82.1)	136 (85.0)
		High value - n (%)	3 (3.8)	2 (4.9)	1 (2.6)	6 (3.8)
		Abnormal CS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS - n (%)	3 (3.8)	2 (4.9)	1 (2.6)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Day 91/Discharge Ambulatory	ALT increased				
		Grade 0 - n (%)	71 (88.8)	34 (82.9)	32 (82.1)	137 (85.6)
		Grade 1 - n (%)	3 (3.8)	2 (4.9)	1 (2.6)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Change from Baseline to Day 91/Discharge Ambulatory	n	74	36	33	143
		Mean (SD)	2.2 (17.46)	0.5 (11.73)	1.3 (11.72)	1.6 (14.90)
		Median	1.0	-1.0	1.0	0.0
		Min, Max	-68, 91	-16, 56	-23, 53	-68, 91

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	68 (85.0)	33 (80.5)	31 (79.5)	132 (82.5)
		Normal to High, NCS - n (%)	1 (1.3)	2 (4.9)	1 (2.6)	4 (2.5)
		Normal to High, CS - n (%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to Normal - n (%)	2 (2.5)	1 (2.4)	1 (2.6)	4 (2.5)
		High, NCS to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alanine aminotransferase (IU/L)	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	ALT increased				
		0 to 0 - n (%)	69 (86.3)	33 (80.5)	31 (79.5)	133 (83.1)
		0 to 1 - n (%)	2 (2.5)	2 (4.9)	1 (2.6)	5 (3.1)
		1 to 0 - n (%)	2 (2.5)	1 (2.4)	1 (2.6)	4 (2.5)
		1 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Baseline	n	80	41	39	160
		Mean (SD)	18.8 (7.05)	17.8 (4.17)	19.4 (4.93)	18.7 (5.93)
		Median	17.5	17.0	19.0	18.0
		Min, Max	10, 60	10, 27	11, 34	10, 60
		Low value - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value - n (%)	77 (96.3)	41 (100)	39 (100)	157 (98.1)
		High value - n (%)	2 (2.5)	0	0	2 (1.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	0	0	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Baseline	AST increased				
		Grade 0 - n (%)	78 (97.5)	41 (100)	39 (100)	158 (98.8)
		Grade 1 - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	18.7 (4.82)	18.2 (4.39)	21.6 (4.63)	19.2 (4.82)
		Median	18.0	18.0	21.0	18.0
		Min, Max	9, 40	11, 28	12, 30	9, 40
		Low value - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value - n (%)	78 (97.5)	40 (97.6)	35 (89.7)	153 (95.6)
		High value - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Day 6/Discharge Confinement	AST increased				
		Grade 0 - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		Grade 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	-0.1 (7.65)	0.6 (4.22)	2.1 (4.88)	0.5 (6.37)
		Median	1.0	0.0	1.0	1.0
		Min, Max	-44, 21	-7, 11	-6, 15	-44, 21

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Low, NCS to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	76 (95.0)	40 (97.6)	35 (89.7)	151 (94.4)
		Normal to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to Normal - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	AST increased				
		0 to 0 - n (%)	77 (96.3)	40 (97.6)	35 (89.7)	152 (95.0)
		0 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)
		1 to 0 - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Day 30	n	76	39	33	148
		Mean (SD)	19.0 (7.13)	19.2 (5.54)	18.9 (4.17)	19.0 (6.14)
		Median	18.0	18.0	19.0	18.0
		Min, Max	9, 46	10, 37	10, 29	9, 46
		Low value - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value - n (%)	71 (88.8)	38 (92.7)	33 (84.6)	142 (88.8)
		High value - n (%)	4 (5.0)	1 (2.4)	0	5 (3.1)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	5 (6.3)	1 (2.4)	0	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Day 30	AST increased				
		Grade 0 - n (%)	72 (90.0)	38 (92.7)	33 (84.6)	143 (89.4)
		Grade 1 - n (%)	4 (5.0)	1 (2.4)	0	5 (3.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Change from Baseline to Day 30	n	76	39	33	148
		Mean (SD)	0.1 (8.66)	1.7 (4.36)	-0.3 (3.17)	0.4 (6.78)
		Median	0.0	1.0	0.0	0.0
		Min, Max	-41, 22	-7, 12	-6, 6	-41, 22

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Shift in Normality from Baseline to Day 30	Low, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	68 (85.0)	38 (92.7)	33 (84.6)	139 (86.9)
		Normal to High, NCS - n (%)	4 (5.0)	1 (2.4)	0	5 (3.1)
		High, NCS to Normal - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Shift in Toxicity from Baseline to Day 30	AST increased				
		0 to 0 - n (%)	70 (87.5)	38 (92.7)	33 (84.6)	141 (88.1)
		0 to 1 - n (%)	4 (5.0)	1 (2.4)	0	5 (3.1)
		1 to 0 - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Day 60	n	74	37	31	142
		Mean (SD)	20.7 (16.41)	16.8 (3.47)	18.5 (4.98)	19.2 (12.27)
		Median	17.0	17.0	18.0	17.0
		Min, Max	10, 109	10, 27	9, 28	9, 109
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	70 (87.5)	37 (90.2)	31 (79.5)	138 (86.3)
		High value - n (%)	4 (5.0)	0	0	4 (2.5)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	0	0	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Day 60	AST increased				
		Grade 0 - n (%)	70 (87.5)	37 (90.2)	31 (79.5)	138 (86.3)
		Grade 1 - n (%)	3 (3.8)	0	0	3 (1.9)
		Grade 2 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	1.8 (16.60)	-1.0 (3.38)	-0.7 (4.07)	0.5 (12.28)
		Median	-0.5	-1.0	-1.0	-1.0
		Min, Max	-33, 87	-8, 5	-10, 7	-33, 87

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	68 (85.0)	37 (90.2)	31 (79.5)	136 (85.0)
		Normal to High, NCS - n (%)	4 (5.0)	0	0	4 (2.5)
		High, NCS to Normal - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Shift in Toxicity from Baseline to Day 60	AST increased				
		0 to 0 - n (%)	68 (85.0)	37 (90.2)	31 (79.5)	136 (85.0)
		0 to 1 - n (%)	3 (3.8)	0	0	3 (1.9)
		0 to 2 - n (%)	1 (1.3)	0	0	1 (0.6)
		1 to 0 - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Day 91/Discharge n Ambulatory		73	36	33	142
		Mean (SD)	21.1 (19.43)	21.4 (18.11)	20.8 (8.43)	21.1 (17.04)
		Median	18.0	18.5	19.0	18.5
		Min, Max	9, 173	12, 125	11, 52	9, 173
		Low value - n (%)	2 (2.5)	0	0	2 (1.3)
		Normal value - n (%)	68 (85.0)	35 (85.4)	31 (79.5)	134 (83.8)
		High value - n (%)	3 (3.8)	1 (2.4)	2 (5.1)	6 (3.8)
		Abnormal CS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS - n (%)	4 (5.0)	1 (2.4)	2 (5.1)	7 (4.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Day 91/Discharge Ambulatory	AST increased				
		Grade 0 - n (%)	70 (87.5)	35 (85.4)	31 (79.5)	136 (85.0)
		Grade 1 - n (%)	2 (2.5)	0	2 (5.1)	4 (2.5)
		Grade 2 - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Change from Baseline to Day 91/Discharge Ambulatory	n	73	36	33	142
		Mean (SD)	2.2 (19.79)	3.5 (18.52)	1.6 (8.69)	2.4 (17.40)
		Median	1.0	1.0	0.0	0.0
		Min, Max	-38, 151	-6, 109	-12, 38	-38, 151

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Low, NCS - n (%)	2 (2.5)	0	0	2 (1.3)
		Normal to Normal - n (%)	66 (82.5)	35 (85.4)	31 (79.5)	132 (82.5)
		Normal to High, NCS - n (%)	2 (2.5)	1 (2.4)	2 (5.1)	5 (3.1)
		Normal to High, CS - n (%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to Normal - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Aspartate aminotransferase (IU/L)	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	AST increased				
		0 to 0 - n (%)	68 (85.0)	35 (85.4)	31 (79.5)	134 (83.8)
		0 to 1 - n (%)	2 (2.5)	0	2 (5.1)	4 (2.5)
		0 to 2 - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		1 to 0 - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Baseline	n	80	41	39	160
		BLOQ, n (%)	1 (1.3)	0	0	1 (0.6)
		Mean (SD)	0.46 (0.173)	0.48 (0.205)	0.47 (0.208)	0.47 (0.189)
		Median	0.40	0.50	0.40	0.40
		Min, Max	0.1, 1.0	0.2, 1.2	0.2, 1.0	0.1, 1.2
		Low value - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value - n (%)	79 (98.8)	41 (100)	39 (100)	159 (99.4)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Baseline	Blood bilirubin increased				
		Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	160 (100)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	0.58 (0.253)	0.53 (0.159)	0.58 (0.296)	0.57 (0.243)
		Median	0.50	0.50	0.50	0.50
		Min, Max	0.2, 1.6	0.2, 0.9	0.3, 1.7	0.2, 1.7
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	78 (97.5)	40 (97.6)	34 (87.2)	152 (95.0)
		High value - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Day 6/Discharge Confinement	Blood bilirubin increased				
		Grade 0 - n (%)	78 (97.5)	40 (97.6)	34 (87.2)	152 (95.0)
		Grade 1 - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	0.12 (0.176)	0.05 (0.144)	0.11 (0.163)	0.10 (0.168)
		Median	0.10	0.10	0.10	0.10
		Min, Max	-0.2, 0.8	-0.3, 0.4	-0.1, 0.7	-0.3, 0.8

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Shift in Normality from Baseline to Day 6/Discharge Confinement	Low, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	77 (96.3)	40 (97.6)	34 (87.2)	151 (94.4)
		Normal to High, NCS - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	Blood bilirubin increased				
		0 to 0 - n (%)	78 (97.5)	40 (97.6)	34 (87.2)	152 (95.0)
		0 to 1 - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Day 30	n	77	39	33	149
		BLOQ, n (%)	1 (1.3)	0	3 (9.1)	4 (2.7)
		Mean (SD)	0.46 (0.229)	0.45 (0.242)	0.42 (0.338)	0.45 (0.259)
		Median	0.40	0.40	0.30	0.40
		Min, Max	0.1, 1.2	0.2, 1.4	0.1, 1.9	0.1, 1.9
		Low value - n (%)	1 (1.3)	0	3 (7.7)	4 (2.5)
		Normal value - n (%)	76 (95.0)	38 (92.7)	29 (74.4)	143 (89.4)
		High value - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	1 (2.4)	4 (10.3)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Day 30	Blood bilirubin increased				
		Grade 0 - n (%)	77 (96.3)	38 (92.7)	32 (82.1)	147 (91.9)
		Grade 1 - n (%)	0	1 (2.4)	0	1 (0.6)
		Grade 2 - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Change from Baseline to Day 30	n	77	39	33	149
		Mean (SD)	0.01 (0.152)	-0.03 (0.144)	-0.05 (0.294)	-0.02 (0.191)
		Median	0.00	-0.10	-0.10	0.00
		Min, Max	-0.3, 0.5	-0.3, 0.3	-0.4, 1.4	-0.4, 1.4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Shift in Normality from Baseline to Day 30	Low, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n (%)	1 (1.3)	0	3 (7.7)	4 (2.5)
		Normal to Normal - n (%)	75 (93.8)	38 (92.7)	29 (74.4)	142 (88.8)
		Normal to High, NCS - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Shift in Toxicity from Baseline to Day 30	Blood bilirubin increased				
		0 to 0 - n (%)	77 (96.3)	38 (92.7)	32 (82.1)	147 (91.9)
		0 to 1 - n (%)	0	1 (2.4)	0	1 (0.6)
		0 to 2 - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Day 60	n	74	37	31	142
		Mean (SD)	0.53 (0.295)	0.51 (0.249)	0.45 (0.170)	0.51 (0.261)
		Median	0.50	0.50	0.40	0.40
		Min, Max	0.2, 2.3	0.2, 1.7	0.2, 0.9	0.2, 2.3
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	73 (91.3)	36 (87.8)	31 (79.5)	140 (87.5)
		High value - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Abnormal CS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Day 60	Blood bilirubin increased				
		Grade 0 - n (%)	73 (91.3)	36 (87.8)	31 (79.5)	140 (87.5)
		Grade 1 - n (%)	0	1 (2.4)	0	1 (0.6)
		Grade 2 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	0.06 (0.244)	0.03 (0.172)	-0.01 (0.157)	0.04 (0.211)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-0.2, 1.8	-0.4, 0.5	-0.4, 0.4	-0.4, 1.8

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Shift in Normality from Baseline to Day 60	Low, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	72 (90.0)	36 (87.8)	31 (79.5)	139 (86.9)
		Normal to High, NCS - n (%)	0	1 (2.4)	0	1 (0.6)
		Normal to High, CS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Shift in Toxicity from Baseline to Day 60	Blood bilirubin increased				
		0 to 0 - n (%)	73 (91.3)	36 (87.8)	31 (79.5)	140 (87.5)
		0 to 1 - n (%)	0	1 (2.4)	0	1 (0.6)
		0 to 2 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Day 91/Discharge n Ambulatory		74	36	33	143
		Mean (SD)	0.57 (0.342)	0.49 (0.179)	0.51 (0.281)	0.54 (0.295)
		Median	0.50	0.50	0.50	0.50
		Min, Max	0.2, 2.2	0.2, 1.1	0.2, 1.6	0.2, 2.2
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	71 (88.8)	36 (87.8)	32 (82.1)	139 (86.9)
		High value - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		Abnormal CS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Day 91/Discharge Ambulatory	Blood bilirubin increased				
		Grade 0 - n (%)	71 (88.8)	36 (87.8)	32 (82.1)	139 (86.9)
		Grade 1 - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)
		Grade 2 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Change from Baseline to Day 91/Discharge Ambulatory	n	74	36	33	143
		Mean (SD)	0.11 (0.275)	0.01 (0.179)	0.05 (0.194)	0.07 (0.240)
		Median	0.10	0.00	0.00	0.00
		Min, Max	-0.5, 1.7	-0.5, 0.3	-0.3, 0.7	-0.5, 1.7

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Low, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	70 (87.5)	36 (87.8)	32 (82.1)	138 (86.3)
		Normal to High, NCS - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)
		Normal to High, CS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (mg/dL) [0.2-1.2]	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	Blood bilirubin increased				
		0 to 0 - n (%)	71 (88.8)	36 (87.8)	32 (82.1)	139 (86.9)
		0 to 1 - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)
		0 to 2 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Direct bilirubin (mg/dL) [0-0.4]	Baseline	n	79	41	39	159
		BLOQ, n (%)	33 (41.8)	14 (34.1)	17 (43.6)	64 (40.3)
		Mean (SD)	0.092 (0.0477)	0.107 (0.0577)	0.094 (0.0516)	0.096 (0.0515)
		Median	0.100	0.100	0.100	0.100
		Min, Max	0.05, 0.20	0.05, 0.20	0.05, 0.20	0.05, 0.20
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	79 (98.8)	41 (100)	39 (100)	159 (99.4)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Direct bilirubin (mg/dL) [0-0.4]	Day 6/Discharge Confinement	n	80	39	35	154
		BLOQ, n (%)	18 (22.5)	10 (25.6)	11 (31.4)	39 (25.3)
		Mean (SD)	0.123 (0.0689)	0.118 (0.0591)	0.113 (0.0732)	0.119 (0.0673)
		Median	0.100	0.100	0.100	0.100
		Min, Max	0.05, 0.40	0.05, 0.20	0.05, 0.40	0.05, 0.40
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	39 (95.1)	35 (89.7)	154 (96.3)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Direct bilirubin (mg/dL) [0-0.4]	Change from Baseline to Day 6/Discharge Confinement	n	79	39	35	153
		Mean (SD)	0.028 (0.0517)	0.013 (0.0510)	0.020 (0.0532)	0.023 (0.0520)
		Median	0.000	0.000	0.000	0.000
		Min, Max	-0.10, 0.20	-0.10, 0.15	-0.10, 0.20	-0.10, 0.20

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Direct bilirubin (mg/dL) [0-0.4]	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Normal - n (%)	79 (98.8)	39 (95.1)	35 (89.7)	153 (95.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Direct bilirubin (mg/dL) [0-0.4]	Day 30	n	75	36	32	143
		BLOQ, n (%)	34 (45.3)	16 (44.4)	19 (59.4)	69 (48.3)
		Mean (SD)	0.099 (0.0621)	0.094 (0.0583)	0.092 (0.0753)	0.096 (0.0640)
		Median	0.100	0.100	0.050	0.100
		Min, Max	0.05, 0.30	0.05, 0.30	0.05, 0.40	0.05, 0.40
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	75 (93.8)	36 (87.8)	32 (82.1)	143 (89.4)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Direct bilirubin (mg/dL) [0-0.4]	Change from Baseline to Day 30	n	74	36	32	142
		Mean (SD)	0.004 (0.0429)	-0.011 (0.0433)	-0.002 (0.0702)	-0.001 (0.0504)
		Median	0.000	0.000	0.000	0.000
		Min, Max	-0.10, 0.15	-0.10, 0.10	-0.10, 0.30	-0.10, 0.30

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Direct bilirubin (mg/dL) [0-0.4]	Shift in Normality from Baseline to Day 30	Normal to Normal - n (%)	74 (92.5)	36 (87.8)	32 (82.1)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Direct bilirubin (mg/dL) [0-0.4]	Day 60	n	74	37	31	142
		BLOQ, n (%)	25 (33.8)	13 (35.1)	15 (48.4)	53 (37.3)
		Mean (SD)	0.113 (0.0900)	0.099 (0.0507)	0.089 (0.0496)	0.104 (0.0740)
		Median	0.100	0.100	0.100	0.100
		Min, Max	0.05, 0.70	0.05, 0.20	0.05, 0.20	0.05, 0.70
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	73 (91.3)	37 (90.2)	31 (79.5)	141 (88.1)
		High value - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Direct bilirubin (mg/dL) [0-0.4]	Change from Baseline to Day 60	n	73	37	31	141
		Mean (SD)	0.020 (0.0721)	-0.011 (0.0502)	-0.003 (0.0407)	0.007 (0.0622)
		Median	0.000	0.000	0.000	0.000
		Min, Max	-0.10, 0.50	-0.15, 0.10	-0.10, 0.10	-0.15, 0.50

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Direct bilirubin (mg/dL) [0-0.4]	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	72 (90.0)	37 (90.2)	31 (79.5)	140 (87.5)
		Normal to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Direct bilirubin (mg/dL) [0-0.4]	Day 91/Discharge n Ambulatory		72	35	33	140
		BLOQ, n (%)	22 (30.6)	12 (34.3)	12 (36.4)	46 (32.9)
		Mean (SD)	0.128 (0.1145)	0.103 (0.0542)	0.112 (0.0719)	0.118 (0.0934)
		Median	0.100	0.100	0.100	0.100
		Min, Max	0.05, 0.90	0.05, 0.20	0.05, 0.30	0.05, 0.90
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	71 (88.8)	35 (85.4)	33 (84.6)	139 (86.9)
		High value - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Direct bilirubin (mg/dL) [0-0.4]	Change from Baseline to Day 91/Discharge Ambulatory	n	71	35	33	139
		Mean (SD)	0.035 (0.0925)	-0.006 (0.0616)	0.018 (0.0412)	0.021 (0.0771)
		Median	0.000	0.000	0.000	0.000
		Min, Max	-0.10, 0.70	-0.15, 0.15	-0.05, 0.10	-0.15, 0.70

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Direct bilirubin (mg/dL) [0-0.4]	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Normal - n (%)	70 (87.5)	35 (85.4)	33 (84.6)	138 (86.3)
		Normal to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Baseline	n	80	41	39	160
		Mean (SD)	68.1 (20.71)	67.0 (20.13)	69.6 (17.12)	68.2 (19.64)
		Median	65.0	65.0	70.0	66.0
		Min, Max	33, 136	36, 116	43, 131	33, 136
		Low value - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value - n (%)	78 (97.5)	41 (100)	38 (97.4)	157 (98.1)
		High value - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Baseline	Alkaline phosphatase increased				
		Grade 0 - n (%)	79 (98.8)	41 (100)	38 (97.4)	158 (98.8)
		Grade 1 - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	69.4 (20.81)	66.9 (19.95)	72.4 (19.36)	69.4 (20.23)
		Median	65.5	62.5	70.0	65.0
		Min, Max	33, 136	35, 127	45, 140	33, 140
		Low value - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value - n (%)	78 (97.5)	40 (97.6)	34 (87.2)	152 (95.0)
		High value - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Day 6/Discharge Confinement	Alkaline phosphatase increased				
		Grade 0 - n (%)	79 (98.8)	40 (97.6)	34 (87.2)	153 (95.6)
		Grade 1 - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	1.3 (5.36)	-0.2 (5.52)	1.9 (4.86)	1.0 (5.32)
		Median	1.0	0.0	1.0	1.0
		Min, Max	-13, 16	-16, 14	-8, 13	-16, 16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Low, NCS to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	78 (97.5)	40 (97.6)	34 (87.2)	152 (95.0)
		High, NCS to High, NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	Alkaline phosphatase increased				
		0 to 0 - n (%)	79 (98.8)	40 (97.6)	34 (87.2)	153 (95.6)
		1 to 1 - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Day 30	n	77	39	33	149
		Mean (SD)	68.3 (20.90)	65.7 (17.40)	69.8 (17.40)	68.0 (19.23)
		Median	64.0	63.0	66.0	64.0
		Min, Max	34, 131	31, 111	43, 119	31, 131
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	75 (93.8)	39 (95.1)	33 (84.6)	147 (91.9)
		High value - n (%)	2 (2.5)	0	0	2 (1.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Day 30	Alkaline phosphatase increased				
		Grade 0 - n (%)	75 (93.8)	39 (95.1)	33 (84.6)	147 (91.9)
		Grade 1 - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Change from Baseline to Day 30	n	77	39	33	149
		Mean (SD)	-0.4 (6.85)	-0.3 (6.60)	-0.2 (6.42)	-0.3 (6.65)
		Median	-1.0	0.0	1.0	0.0
		Min, Max	-18, 19	-22, 13	-12, 14	-22, 19

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Shift in Normality from Baseline to Day 30	Low, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	74 (92.5)	39 (95.1)	32 (82.1)	145 (90.6)
		Normal to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to Normal - n (%)	0	0	1 (2.6)	1 (0.6)
		High, NCS to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Shift in Toxicity from Baseline to Day 30	Alkaline phosphatase increased				
		0 to 0 - n (%)	75 (93.8)	39 (95.1)	32 (82.1)	146 (91.3)
		0 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)
		1 to 0 - n (%)	0	0	1 (2.6)	1 (0.6)
		1 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Day 60	n	74	37	31	142
		Mean (SD)	67.9 (20.90)	65.8 (19.41)	70.5 (19.44)	67.9 (20.13)
		Median	64.0	63.0	70.0	64.0
		Min, Max	33, 128	31, 116	43, 121	31, 128
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	73 (91.3)	37 (90.2)	31 (79.5)	141 (88.1)
		High value - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Day 60	Alkaline phosphatase increased				
		Grade 0 - n (%)	73 (91.3)	37 (90.2)	31 (79.5)	141 (88.1)
		Grade 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	-0.2 (8.12)	-1.9 (6.85)	0.7 (6.65)	-0.5 (7.51)
		Median	-1.0	-1.0	1.0	-1.0
		Min, Max	-19, 21	-31, 10	-12, 18	-31, 21

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Shift in Normality from Baseline to Day 60	Low, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	72 (90.0)	37 (90.2)	30 (76.9)	139 (86.9)
		High, NCS to Normal - n (%)	0	0	1 (2.6)	1 (0.6)
		High, NCS to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Shift in Toxicity from Baseline to Day 60	Alkaline phosphatase increased				
		0 to 0 - n (%)	73 (91.3)	37 (90.2)	30 (76.9)	140 (87.5)
		1 to 0 - n (%)	0	0	1 (2.6)	1 (0.6)
		1 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Day 91/Discharge n Ambulatory		74	36	33	143
		Mean (SD)	69.9 (21.80)	68.5 (18.04)	73.1 (20.39)	70.3 (20.52)
		Median	66.5	66.0	69.0	67.0
		Min, Max	36, 134	35, 113	47, 133	35, 134
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	72 (90.0)	36 (87.8)	31 (79.5)	139 (86.9)
		High value - n (%)	2 (2.5)	0	2 (5.1)	4 (2.5)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	0	2 (5.1)	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Day 91/Discharge Ambulatory	Alkaline phosphatase increased				
		Grade 0 - n (%)	72 (90.0)	36 (87.8)	31 (79.5)	139 (86.9)
		Grade 1 - n (%)	2 (2.5)	0	2 (5.1)	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Change from Baseline to Day 91/Discharge Ambulatory	n	74	36	33	143
		Mean (SD)	1.6 (7.26)	0.5 (7.31)	3.2 (7.14)	1.7 (7.26)
		Median	1.0	2.0	4.0	2.0
		Min, Max	-14, 26	-17, 21	-12, 17	-17, 26

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Low, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	71 (88.8)	36 (87.8)	31 (79.5)	138 (86.3)
		Normal to High, NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		High, NCS to High, NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Alkaline phosphatase (IU/L)	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	Alkaline phosphatase increased				
		0 to 0 - n (%)	72 (90.0)	36 (87.8)	31 (79.5)	139 (86.9)
		0 to 1 - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		1 to 1 - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Baseline	n	80	41	39	160
		Mean (SD)	24.0 (17.68)	20.7 (14.71)	23.3 (10.87)	23.0 (15.49)
		Median	19.0	16.0	21.0	18.0
		Min, Max	5, 126	7, 89	11, 55	5, 126
		Low value - n (%)	2 (2.5)	0	0	2 (1.3)
		Normal value - n (%)	74 (92.5)	40 (97.6)	39 (100)	153 (95.6)
		High value - n (%)	4 (5.0)	1 (2.4)	0	5 (3.1)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	6 (7.5)	1 (2.4)	0	7 (4.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Baseline	GGT increased				
		Grade 0 - n (%)	76 (95.0)	40 (97.6)	39 (100)	155 (96.9)
		Grade 1 - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		Grade 2 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	24.0 (16.14)	21.4 (17.35)	23.7 (10.04)	23.2 (15.28)
		Median	19.0	17.0	21.0	19.0
		Min, Max	7, 103	7, 116	13, 49	7, 116
		Low value - n (%)	2 (2.5)	0	0	2 (1.3)
		Normal value - n (%)	75 (93.8)	39 (95.1)	35 (89.7)	149 (93.1)
		High value - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	5 (6.3)	1 (2.4)	0	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Day 6/Discharge Confinement	GGT increased				
		Grade 0 - n (%)	77 (96.3)	39 (95.1)	35 (89.7)	151 (94.4)
		Grade 1 - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US

Program: t_labchem.sas

Status: Final

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	0.0 (5.44)	0.5 (6.49)	0.2 (4.97)	0.2 (5.60)
		Median	0.0	0.0	0.0	0.0
		Min, Max	-23, 15	-13, 27	-14, 12	-23, 27

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US

Program: t_labchem.sas

Status: Final

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Low, NCS to Low, NCS - n (%)	2 (2.5)	0	0	2 (1.3)
		Normal to Normal - n (%)	73 (91.3)	39 (95.1)	35 (89.7)	147 (91.9)
		Normal to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to Normal - n (%)	2 (2.5)	0	0	2 (1.3)
		High, NCS to High, NCS - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	GGT increased				
		0 to 0 - n (%)	75 (93.8)	39 (95.1)	35 (89.7)	149 (93.1)
		0 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)
		1 to 0 - n (%)	2 (2.5)	0	0	2 (1.3)
		1 to 1 - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		2 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Day 30	n	77	39	33	149
		Mean (SD)	24.1 (17.26)	22.6 (18.13)	23.8 (12.60)	23.6 (16.49)
		Median	19.0	16.0	21.0	19.0
		Min, Max	5, 94	6, 91	9, 66	5, 94
		Low value - n (%)	2 (2.5)	1 (2.4)	1 (2.6)	4 (2.5)
		Normal value - n (%)	72 (90.0)	36 (87.8)	31 (79.5)	139 (86.9)
		High value - n (%)	3 (3.8)	2 (4.9)	1 (2.6)	6 (3.8)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	5 (6.3)	3 (7.3)	2 (5.1)	10 (6.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Day 30	GGT increased				
		Grade 0 - n (%)	74 (92.5)	37 (90.2)	32 (82.1)	143 (89.4)
		Grade 1 - n (%)	3 (3.8)	2 (4.9)	1 (2.6)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Change from Baseline to Day 30	n	77	39	33	149
		Mean (SD)	-0.1 (10.69)	1.6 (8.28)	0.1 (7.32)	0.4 (9.41)
		Median	0.0	0.0	-1.0	0.0
		Min, Max	-38, 56	-10, 47	-14, 26	-38, 56

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Shift in Normality from Baseline to Day 30	Low, NCS to Low, NCS - n (%)	2 (2.5)	0	0	2 (1.3)
		Normal to Low, NCS - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
		Normal to Normal - n (%)	70 (87.5)	36 (87.8)	31 (79.5)	137 (85.6)
		Normal to High, NCS - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		High, NCS to Normal - n (%)	2 (2.5)	0	0	2 (1.3)
		High, NCS to High, NCS - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Shift in Toxicity from Baseline to Day 30	GGT increased				
		0 to 0 - n (%)	72 (90.0)	37 (90.2)	32 (82.1)	141 (88.1)
		0 to 1 - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		1 to 0 - n (%)	2 (2.5)	0	0	2 (1.3)
		1 to 1 - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		2 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Day 60	n	74	37	31	142
		Mean (SD)	29.6 (49.69)	21.8 (15.04)	24.4 (14.03)	26.4 (37.28)
		Median	20.5	16.0	22.0	20.0
		Min, Max	5, 434	9, 75	10, 69	5, 434
		Low value - n (%)	2 (2.5)	0	0	2 (1.3)
		Normal value - n (%)	68 (85.0)	35 (85.4)	29 (74.4)	132 (82.5)
		High value - n (%)	4 (5.0)	2 (4.9)	2 (5.1)	8 (5.0)
		Abnormal CS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS - n (%)	5 (6.3)	2 (4.9)	2 (5.1)	9 (5.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Day 60	GGT increased				
		Grade 0 - n (%)	70 (87.5)	35 (85.4)	29 (74.4)	134 (83.8)
		Grade 1 - n (%)	3 (3.8)	2 (4.9)	2 (5.1)	7 (4.4)
		Grade 3 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US Program: t_labchem.sas Status: Final

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	5.4 (36.28)	0.3 (6.81)	0.8 (6.86)	3.0 (26.63)
		Median	1.0	1.0	-1.0	0.0
		Min, Max	-15, 308	-18, 27	-7, 23	-18, 308

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Shift in Normality from Baseline to Day 60	Low, NCS to Low, NCS - n (%)	2 (2.5)	0	0	2 (1.3)
		Normal to Normal - n (%)	67 (83.8)	35 (85.4)	29 (74.4)	131 (81.9)
		Normal to High, NCS - n (%)	1 (1.3)	1 (2.4)	2 (5.1)	4 (2.5)
		High, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to High, NCS - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		High, NCS to High, CS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Shift in Toxicity from Baseline to Day 60	GGT increased				
		0 to 0 - n (%)	69 (86.3)	35 (85.4)	29 (74.4)	133 (83.1)
		0 to 1 - n (%)	1 (1.3)	1 (2.4)	2 (5.1)	4 (2.5)
		1 to 0 - n (%)	1 (1.3)	0	0	1 (0.6)
		1 to 1 - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		2 to 3 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Day 91/Discharge n Ambulatory		74	36	33	143
		Mean (SD)	36.6 (93.09)	24.6 (20.01)	24.3 (12.43)	30.7 (68.01)
		Median	21.0	17.5	20.0	19.0
		Min, Max	7, 812	10, 111	11, 69	7, 812
		Low value - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value - n (%)	69 (86.3)	34 (82.9)	32 (82.1)	135 (84.4)
		High value - n (%)	4 (5.0)	2 (4.9)	1 (2.6)	7 (4.4)
		Abnormal CS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS - n (%)	4 (5.0)	2 (4.9)	1 (2.6)	7 (4.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US Program: t_labchem.sas Status: Final

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Day 91/Discharge Ambulatory	GGT increased				
		Grade 0 - n (%)	70 (87.5)	34 (82.9)	32 (82.1)	136 (85.0)
		Grade 1 - n (%)	3 (3.8)	2 (4.9)	1 (2.6)	6 (3.8)
		Grade 3 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US Program: t_labchem.sas Status: Final

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Change from Baseline to Day 91/Discharge Ambulatory	n	74	36	33	143
		Mean (SD)	12.3 (80.09)	2.7 (7.88)	0.6 (7.30)	7.2 (57.91)
		Median	2.0	1.0	-1.0	1.0
		Min, Max	-38, 686	-16, 35	-11, 23	-38, 686

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US

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Status: Final

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Low, NCS to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Low, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	66 (82.5)	34 (82.9)	32 (82.1)	132 (82.5)
		Normal to High, NCS - n (%)	2 (2.5)	1 (2.4)	1 (2.6)	4 (2.5)
		High, NCS to Normal - n (%)	2 (2.5)	0	0	2 (1.3)
		High, NCS to High, NCS - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		High, NCS to High, CS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Gamma glutamyl transferase (IU/L)	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	GGT increased				
		0 to 0 - n (%)	68 (85.0)	34 (82.9)	32 (82.1)	134 (83.8)
		0 to 1 - n (%)	2 (2.5)	1 (2.4)	1 (2.6)	4 (2.5)
		1 to 0 - n (%)	2 (2.5)	0	0	2 (1.3)
		1 to 1 - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		2 to 3 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Baseline	n	55	28	31	114
		Mean (SD)	95.3 (7.57)	94.9 (8.50)	95.1 (8.82)	95.1 (8.08)
		Median	95.0	94.0	94.0	94.0
		Min, Max	83, 118	83, 116	81, 113	81, 118
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	43 (53.8)	22 (53.7)	23 (59.0)	88 (55.0)
		High value - n (%)	12 (15.0)	6 (14.6)	8 (20.5)	26 (16.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	12 (15.0)	6 (14.6)	8 (20.5)	26 (16.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Baseline	Hyperglycemia				
		Grade 0 - n (%)	43 (53.8)	22 (53.7)	23 (59.0)	88 (55.0)
		Grade 1 - n (%)	12 (15.0)	6 (14.6)	8 (20.5)	26 (16.3)
		Hypoglycemia				
		Grade 0 - n (%)	55 (68.8)	28 (68.3)	31 (79.5)	114 (71.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Day 6/Discharge Confinement	n	79	40	35	154
		Mean (SD)	89.4 (8.86)	85.1 (5.17)	90.6 (8.57)	88.6 (8.23)
		Median	88.0	85.0	90.0	87.0
		Min, Max	75, 139	74, 97	72, 115	72, 139
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	40 (97.6)	32 (82.1)	146 (91.3)
		High value - n (%)	5 (6.3)	0	3 (7.7)	8 (5.0)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	5 (6.3)	0	3 (7.7)	8 (5.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Day 6/Discharge Confinement	Hyperglycemia				
		Grade 0 - n (%)	74 (92.5)	40 (97.6)	32 (82.1)	146 (91.3)
		Grade 1 - n (%)	5 (6.3)	0	3 (7.7)	8 (5.0)
		Hypoglycemia				
		Grade 0 - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Change from Baseline to Day 6/Discharge Confinement	n	79	40	35	154
		Mean (SD)	-4.7 (8.91)	-8.8 (6.64)	-4.5 (7.37)	-5.7 (8.19)
		Median	-4.0	-9.0	-4.0	-5.0
		Min, Max	-22, 48	-24, 7	-25, 9	-25, 48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Normal - n (%)	62 (77.5)	34 (82.9)	27 (69.2)	123 (76.9)
		Normal to High, NCS - n (%)	2 (2.5)	0	0	2 (1.3)
		High, NCS to Normal - n (%)	12 (15.0)	6 (14.6)	5 (12.8)	23 (14.4)
		High, NCS to High, NCS - n (%)	3 (3.8)	0	3 (7.7)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	Hyperglycemia				
		0 to 0 - n (%)	62 (77.5)	34 (82.9)	27 (69.2)	123 (76.9)
		0 to 1 - n (%)	2 (2.5)	0	0	2 (1.3)
		1 to 0 - n (%)	12 (15.0)	6 (14.6)	5 (12.8)	23 (14.4)
		1 to 1 - n (%)	3 (3.8)	0	3 (7.7)	6 (3.8)
		Hypoglycemia				
		0 to 0 - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Day 30	n	76	38	31	145
		Mean (SD)	93.8 (7.50)	92.6 (5.92)	94.1 (12.16)	93.6 (8.33)
		Median	93.0	93.5	91.0	93.0
		Min, Max	77, 120	78, 103	83, 147	77, 147
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	62 (77.5)	35 (85.4)	26 (66.7)	123 (76.9)
		High value - n (%)	14 (17.5)	3 (7.3)	5 (12.8)	22 (13.8)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	14 (17.5)	3 (7.3)	5 (12.8)	22 (13.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Day 30	Hyperglycemia				
		Grade 0 - n (%)	62 (77.5)	35 (85.4)	26 (66.7)	123 (76.9)
		Grade 1 - n (%)	14 (17.5)	3 (7.3)	5 (12.8)	22 (13.8)
		Hypoglycemia				
		Grade 0 - n (%)	76 (95.0)	38 (92.7)	31 (79.5)	145 (90.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Change from Baseline to Day 30	n	76	38	31	145
		Mean (SD)	-0.5 (6.13)	-1.6 (6.04)	-0.4 (5.50)	-0.8 (5.96)
		Median	0.0	-1.5	0.0	-1.0
		Min, Max	-16, 17	-17, 9	-12, 15	-17, 17

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Shift in Normality from Baseline to Day 30	Normal to Normal - n (%)	55 (68.8)	32 (78.0)	25 (64.1)	112 (70.0)
		Normal to High, NCS - n (%)	7 (8.8)	0	0	7 (4.4)
		High, NCS to Normal - n (%)	7 (8.8)	3 (7.3)	1 (2.6)	11 (6.9)
		High, NCS to High, NCS - n (%)	7 (8.8)	3 (7.3)	5 (12.8)	15 (9.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Shift in Toxicity from Baseline to Day 30	Hyperglycemia				
		0 to 0 - n (%)	55 (68.8)	32 (78.0)	25 (64.1)	112 (70.0)
		0 to 1 - n (%)	7 (8.8)	0	0	7 (4.4)
		1 to 0 - n (%)	7 (8.8)	3 (7.3)	1 (2.6)	11 (6.9)
		1 to 1 - n (%)	7 (8.8)	3 (7.3)	5 (12.8)	15 (9.4)
		Hypoglycemia				
		0 to 0 - n (%)	76 (95.0)	38 (92.7)	31 (79.5)	145 (90.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Day 60	n	72	36	30	138
		Mean (SD)	93.5 (8.70)	91.8 (7.49)	98.0 (16.68)	94.1 (10.83)
		Median	94.0	91.0	94.5	93.0
		Min, Max	72, 124	77, 114	80, 173	72, 173
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	61 (76.3)	31 (75.6)	22 (56.4)	114 (71.3)
		High value - n (%)	11 (13.8)	5 (12.2)	8 (20.5)	24 (15.0)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	11 (13.8)	5 (12.2)	8 (20.5)	24 (15.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Day 60	Hyperglycemia				
		Grade 0 - n (%)	61 (76.3)	31 (75.6)	22 (56.4)	114 (71.3)
		Grade 1 - n (%)	11 (13.8)	5 (12.2)	7 (17.9)	23 (14.4)
		Grade 2 - n (%)	0	0	1 (2.6)	1 (0.6)
		Hypoglycemia				
		Grade 0 - n (%)	72 (90.0)	36 (87.8)	30 (76.9)	138 (86.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Change from Baseline to Day 60	n	72	36	30	138
		Mean (SD)	-0.7 (7.28)	-2.8 (8.08)	2.9 (10.18)	-0.4 (8.36)
		Median	0.0	-3.0	2.5	-1.0
		Min, Max	-19, 15	-23, 19	-18, 41	-23, 41

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	54 (67.5)	29 (70.7)	20 (51.3)	103 (64.4)
		Normal to High, NCS - n (%)	5 (6.3)	1 (2.4)	3 (7.7)	9 (5.6)
		High, NCS to Normal - n (%)	7 (8.8)	2 (4.9)	2 (5.1)	11 (6.9)
		High, NCS to High, NCS - n (%)	6 (7.5)	4 (9.8)	5 (12.8)	15 (9.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Shift in Toxicity from Baseline to Day 60	Hyperglycemia				
		0 to 0 - n (%)	54 (67.5)	29 (70.7)	20 (51.3)	103 (64.4)
		0 to 1 - n (%)	5 (6.3)	1 (2.4)	3 (7.7)	9 (5.6)
		1 to 0 - n (%)	7 (8.8)	2 (4.9)	2 (5.1)	11 (6.9)
		1 to 1 - n (%)	6 (7.5)	4 (9.8)	4 (10.3)	14 (8.8)
		1 to 2 - n (%)	0	0	1 (2.6)	1 (0.6)
		Hypoglycemia				
		0 to 0 - n (%)	72 (90.0)	36 (87.8)	30 (76.9)	138 (86.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Day 91/Discharge n Ambulatory		74	35	33	142
		Mean (SD)	94.1 (8.19)	92.3 (7.27)	97.0 (14.81)	94.3 (10.00)
		Median	93.5	93.0	95.0	93.5
		Min, Max	81, 127	77, 113	79, 168	77, 168
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	58 (72.5)	32 (78.0)	24 (61.5)	114 (71.3)
		High value - n (%)	16 (20.0)	3 (7.3)	9 (23.1)	28 (17.5)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	16 (20.0)	3 (7.3)	9 (23.1)	28 (17.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Day 91/Discharge Ambulatory	Hyperglycemia				
		Grade 0 - n (%)	58 (72.5)	32 (78.0)	24 (61.5)	114 (71.3)
		Grade 1 - n (%)	16 (20.0)	3 (7.3)	8 (20.5)	27 (16.9)
		Grade 2 - n (%)	0	0	1 (2.6)	1 (0.6)
		Hypoglycemia				
		Grade 0 - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Change from Baseline to Day 91/Discharge Ambulatory	n	74	35	33	142
		Mean (SD)	-0.2 (7.66)	-2.6 (10.50)	2.3 (8.68)	-0.2 (8.77)
		Median	-1.0	-4.0	2.0	-1.0
		Min, Max	-19, 29	-39, 21	-10, 36	-39, 36

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Normal - n (%)	48 (60.0)	26 (63.4)	22 (56.4)	96 (60.0)
		Normal to High, NCS - n (%)	11 (13.8)	3 (7.3)	4 (10.3)	18 (11.3)
		High, NCS to Normal - n (%)	10 (12.5)	6 (14.6)	2 (5.1)	18 (11.3)
		High, NCS to High, NCS - n (%)	5 (6.3)	0	5 (12.8)	10 (6.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (mg/dL) [70-100]	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	Hyperglycemia				
		0 to 0 - n (%)	48 (60.0)	26 (63.4)	22 (56.4)	96 (60.0)
		0 to 1 - n (%)	11 (13.8)	3 (7.3)	4 (10.3)	18 (11.3)
		1 to 0 - n (%)	10 (12.5)	6 (14.6)	2 (5.1)	18 (11.3)
		1 to 1 - n (%)	5 (6.3)	0	4 (10.3)	9 (5.6)
		1 to 2 - n (%)	0	0	1 (2.6)	1 (0.6)
		Hypoglycemia				
		0 to 0 - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Baseline	n	80	41	39	160
		Mean (SD)	0.930 (0.1634)	0.971 (0.2695)	0.926 (0.1698)	0.939 (0.1969)
		Median	0.900	0.900	0.900	0.900
		Min, Max	0.60, 1.30	0.70, 2.30	0.60, 1.30	0.60, 2.30
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	79 (98.8)	39 (95.1)	38 (97.4)	156 (97.5)
		High value - n (%)	1 (1.3)	2 (4.9)	1 (2.6)	4 (2.5)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	2 (4.9)	1 (2.6)	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Baseline	Creatinine increased				
		Grade 0 - n (%)	79 (98.8)	39 (95.1)	38 (97.4)	156 (97.5)
		Grade 1 - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		Grade 2 - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	1.006 (0.1672)	0.985 (0.1982)	1.009 (0.1976)	1.001 (0.1817)
		Median	1.000	0.900	1.000	1.000
		Min, Max	0.70, 1.40	0.60, 1.40	0.70, 1.40	0.60, 1.40
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	34 (82.9)	30 (76.9)	138 (86.3)
		High value - n (%)	6 (7.5)	6 (14.6)	5 (12.8)	17 (10.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	6 (7.5)	6 (14.6)	5 (12.8)	17 (10.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Day 6/Discharge Confinement	Creatinine increased				
		Grade 0 - n (%)	24 (30.0)	23 (56.1)	13 (33.3)	60 (37.5)
		Grade 1 - n (%)	56 (70.0)	17 (41.5)	22 (56.4)	95 (59.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	0.076 (0.0784)	0.010 (0.2274)	0.077 (0.0808)	0.059 (0.1362)
		Median	0.100	0.000	0.100	0.100
		Min, Max	-0.10, 0.30	-1.30, 0.30	-0.10, 0.20	-1.30, 0.30

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Normal - n (%)	74 (92.5)	33 (80.5)	30 (76.9)	137 (85.6)
		Normal to High, NCS - n (%)	5 (6.3)	5 (12.2)	4 (10.3)	14 (8.8)
		High, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)
		High, NCS to High, NCS - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	Creatinine increased				
		0 to 0 - n (%)	24 (30.0)	22 (53.7)	13 (33.3)	59 (36.9)
		0 to 1 - n (%)	55 (68.8)	16 (39.0)	21 (53.8)	92 (57.5)
		1 to 1 - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		2 to 0 - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Day 30	n	77	39	33	149
		Mean (SD)	0.927 (0.1587)	0.949 (0.1731)	0.930 (0.2008)	0.934 (0.1715)
		Median	0.900	0.900	0.900	0.900
		Min, Max	0.60, 1.20	0.60, 1.30	0.50, 1.30	0.50, 1.30
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	77 (96.3)	38 (92.7)	31 (79.5)	146 (91.3)
		High value - n (%)	0	1 (2.4)	2 (5.1)	3 (1.9)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	2 (5.1)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Day 30	Creatinine increased				
		Grade 0 - n (%)	56 (70.0)	29 (70.7)	24 (61.5)	109 (68.1)
		Grade 1 - n (%)	21 (26.3)	10 (24.4)	9 (23.1)	40 (25.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Change from Baseline to Day 30	n	77	39	33	149
		Mean (SD)	-0.005 (0.0826)	-0.031 (0.2227)	-0.003 (0.0770)	-0.011 (0.1329)
		Median	0.000	0.000	0.000	0.000
		Min, Max	-0.20, 0.10	-1.30, 0.20	-0.10, 0.10	-1.30, 0.20

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Shift in Normality from Baseline to Day 30	Normal to Normal - n (%)	76 (95.0)	36 (87.8)	30 (76.9)	142 (88.8)
		Normal to High, NCS - n (%)	0	1 (2.4)	2 (5.1)	3 (1.9)
		High, NCS to Normal - n (%)	1 (1.3)	2 (4.9)	1 (2.6)	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Shift in Toxicity from Baseline to Day 30	Creatinine increased				
		0 to 0 - n (%)	55 (68.8)	27 (65.9)	23 (59.0)	105 (65.6)
		0 to 1 - n (%)	21 (26.3)	10 (24.4)	9 (23.1)	40 (25.0)
		1 to 0 - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		2 to 0 - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Day 60	n	74	37	31	142
		Mean (SD)	0.931 (0.1579)	0.959 (0.2034)	0.945 (0.2014)	0.942 (0.1796)
		Median	0.900	1.000	0.900	0.900
		Min, Max	0.60, 1.30	0.60, 1.50	0.60, 1.30	0.60, 1.50
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	34 (82.9)	28 (71.8)	136 (85.0)
		High value - n (%)	0	3 (7.3)	3 (7.7)	6 (3.8)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	3 (7.3)	3 (7.7)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Day 60	Creatinine increased				
		Grade 0 - n (%)	51 (63.8)	24 (58.5)	20 (51.3)	95 (59.4)
		Grade 1 - n (%)	23 (28.8)	13 (31.7)	11 (28.2)	47 (29.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	0.014 (0.0689)	-0.027 (0.2353)	0.016 (0.0821)	0.004 (0.1355)
		Median	0.000	0.000	0.000	0.000
		Min, Max	-0.10, 0.10	-1.30, 0.30	-0.20, 0.20	-1.30, 0.30

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	74 (92.5)	33 (80.5)	28 (71.8)	135 (84.4)
		Normal to High, NCS - n (%)	0	2 (4.9)	2 (5.1)	4 (2.5)
		High, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)
		High, NCS to High, NCS - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Shift in Toxicity from Baseline to Day 60	Creatinine increased				
		0 to 0 - n (%)	51 (63.8)	23 (56.1)	20 (51.3)	94 (58.8)
		0 to 1 - n (%)	23 (28.8)	12 (29.3)	10 (25.6)	45 (28.1)
		1 to 1 - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
		2 to 0 - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Day 91/Discharge n Ambulatory		74	36	33	143
		Mean (SD)	0.946 (0.1777)	0.947 (0.1844)	0.952 (0.1890)	0.948 (0.1807)
		Median	0.900	0.900	0.900	0.900
		Min, Max	0.60, 1.40	0.60, 1.40	0.60, 1.30	0.60, 1.40
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	72 (90.0)	34 (82.9)	31 (79.5)	137 (85.6)
		High value - n (%)	2 (2.5)	2 (4.9)	2 (5.1)	6 (3.8)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	2 (4.9)	2 (5.1)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Day 91/Discharge Ambulatory	Creatinine increased				
		Grade 0 - n (%)	47 (58.8)	27 (65.9)	21 (53.8)	95 (59.4)
		Grade 1 - n (%)	27 (33.8)	9 (22.0)	12 (30.8)	48 (30.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Change from Baseline to Day 91/Discharge Ambulatory	n	74	36	33	143
		Mean (SD)	0.024 (0.0873)	-0.003 (0.0811)	0.018 (0.0847)	0.016 (0.0853)
		Median	0.000	0.000	0.000	0.000
		Min, Max	-0.20, 0.20	-0.10, 0.20	-0.10, 0.20	-0.20, 0.20

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Normal - n (%)	72 (90.0)	33 (80.5)	31 (79.5)	136 (85.0)
		Normal to High, NCS - n (%)	2 (2.5)	2 (4.9)	1 (2.6)	5 (3.1)
		High, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)
		High, NCS to High, NCS - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Creatinine (mg/dL)	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	Creatinine increased				
		0 to 0 - n (%)	47 (58.8)	26 (63.4)	21 (53.8)	94 (58.8)
		0 to 1 - n (%)	27 (33.8)	9 (22.0)	11 (28.2)	47 (29.4)
		1 to 0 - n (%)	0	1 (2.4)	0	1 (0.6)
		1 to 1 - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Baseline	n	80	41	39	160
		Mean (SD)	7.12 (0.430)	7.21 (0.504)	7.19 (0.477)	7.16 (0.460)
		Median	7.00	7.20	7.30	7.10
		Min, Max	6.3, 8.4	6.4, 9.3	6.1, 8.1	6.1, 9.3
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	40 (97.6)	39 (100)	159 (99.4)
		High value - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Baseline	Hypoproteinemia Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	160 (100)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	7.21 (0.360)	7.11 (0.442)	7.22 (0.376)	7.19 (0.387)
		Median	7.20	7.05	7.20	7.20
		Min, Max	6.5, 8.1	6.4, 8.7	6.6, 8.0	6.4, 8.7
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	39 (95.1)	35 (89.7)	154 (96.3)
		High value - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Day 6/Discharge Confinement	Hypoproteinemia Grade 0 - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	0.09 (0.298)	-0.11 (0.337)	-0.01 (0.373)	0.02 (0.336)
		Median	0.10	-0.20	0.00	0.00
		Min, Max	-0.6, 0.7	-0.7, 0.6	-1.0, 0.7	-1.0, 0.7

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Normal - n (%)	80 (100)	39 (95.1)	35 (89.7)	154 (96.3)
		High, NCS to High, NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	Hypoproteinemia 0 to 0 - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Day 30	n	77	39	33	149
		Mean (SD)	6.98 (0.448)	7.01 (0.434)	7.03 (0.420)	7.00 (0.436)
		Median	7.00	7.00	7.00	7.00
		Min, Max	6.0, 8.3	5.7, 7.8	6.0, 8.2	5.7, 8.3
		Low value - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		Normal value - n (%)	76 (95.0)	38 (92.7)	32 (82.1)	146 (91.3)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Day 30	Hypoproteinemia				
		Grade 0 - n (%)	76 (95.0)	38 (92.7)	32 (82.1)	146 (91.3)
		Grade 1 - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Change from Baseline to Day 30	n	77	39	33	149
		Mean (SD)	-0.14 (0.390)	-0.21 (0.421)	-0.19 (0.469)	-0.17 (0.415)
		Median	-0.20	-0.20	-0.30	-0.20
		Min, Max	-1.1, 0.9	-1.5, 0.6	-1.2, 1.0	-1.5, 1.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Shift in Normality from Baseline to Day 30	Normal to Low, NCS - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		Normal to Normal - n (%)	76 (95.0)	37 (90.2)	32 (82.1)	145 (90.6)
		High, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Shift in Toxicity from Baseline to Day 30	Hypoproteinemia				
		0 to 0 - n (%)	76 (95.0)	38 (92.7)	32 (82.1)	146 (91.3)
		0 to 1 - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Day 60	n	74	37	31	142
		Mean (SD)	7.02 (0.436)	6.99 (0.461)	7.05 (0.545)	7.02 (0.465)
		Median	7.00	7.00	7.10	7.00
		Min, Max	6.0, 8.0	5.6, 8.1	6.0, 8.1	5.6, 8.1
		Low value - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		Normal value - n (%)	73 (91.3)	36 (87.8)	30 (76.9)	139 (86.9)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Day 60	Hypoproteinemia				
		Grade 0 - n (%)	73 (91.3)	36 (87.8)	30 (76.9)	139 (86.9)
		Grade 1 - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	-0.11 (0.406)	-0.23 (0.516)	-0.17 (0.526)	-0.16 (0.463)
		Median	-0.10	-0.10	-0.20	-0.10
		Min, Max	-1.0, 1.0	-2.5, 0.5	-1.1, 1.1	-2.5, 1.1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Shift in Normality from Baseline to Day 60	Normal to Low, NCS - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		Normal to Normal - n (%)	73 (91.3)	35 (85.4)	30 (76.9)	138 (86.3)
		High, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Shift in Toxicity from Baseline to Day 60	Hypoproteinemia				
		0 to 0 - n (%)	73 (91.3)	36 (87.8)	30 (76.9)	139 (86.9)
		0 to 1 - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Day 91/Discharge n Ambulatory		74	36	33	143
		Mean (SD)	7.30 (0.433)	7.27 (0.455)	7.26 (0.409)	7.29 (0.430)
		Median	7.30	7.20	7.40	7.30
		Min, Max	6.3, 8.2	6.4, 8.5	6.5, 8.0	6.3, 8.5
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)
		High value - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Day 91/Discharge Ambulatory	Hypoproteinemia Grade 0 - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Change from Baseline to Day 91/Discharge Ambulatory	n	74	36	33	143
		Mean (SD)	0.17 (0.428)	0.05 (0.535)	0.04 (0.481)	0.11 (0.470)
		Median	0.10	0.10	0.00	0.10
		Min, Max	-0.8, 1.1	-2.2, 1.1	-0.7, 1.4	-2.2, 1.4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Normal - n (%)	74 (92.5)	34 (82.9)	33 (84.6)	141 (88.1)
		Normal to High, NCS - n (%)	0	1 (2.4)	0	1 (0.6)
		High, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (g/dL)	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	Hypoproteinemia 0 to 0 - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Baseline	n	80	41	39	160
		Mean (SD)	14.2 (2.89)	14.2 (2.59)	14.0 (2.79)	14.2 (2.78)
		Median	14.0	14.0	14.0	14.0
		Min, Max	8, 22	9, 20	6, 19	6, 22
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	160 (100)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Baseline	Blood Urea Nitrogen				
		Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	160 (100)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	15.0 (3.24)	14.1 (2.79)	15.3 (3.16)	14.9 (3.12)
		Median	15.0	14.0	15.0	14.0
		Min, Max	9, 25	9, 21	7, 21	7, 25
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		High value - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Day 6/Discharge Confinement	Blood Urea Nitrogen				
		Grade 0 - n (%)	78 (97.5)	40 (97.6)	35 (89.7)	153 (95.6)
		Grade 1 - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	0.8 (2.77)	-0.2 (2.25)	1.1 (2.04)	0.6 (2.53)
		Median	1.0	0.0	1.0	1.0
		Min, Max	-7, 8	-5, 5	-3, 6	-7, 8

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		Normal to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	Blood Urea Nitrogen				
		0 to 0 - n (%)	78 (97.5)	40 (97.6)	35 (89.7)	153 (95.6)
		0 to 1 - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Day 30	n	77	39	33	149
		Mean (SD)	12.9 (2.71)	12.9 (2.15)	14.3 (4.01)	13.2 (2.97)
		Median	13.0	12.0	13.0	13.0
		Min, Max	9, 19	9, 18	6, 26	6, 26
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)
		High value - n (%)	0	0	1 (2.6)	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Day 30	Blood Urea Nitrogen				
		Grade 0 - n (%)	77 (96.3)	39 (95.1)	31 (79.5)	147 (91.9)
		Grade 1 - n (%)	0	0	2 (5.1)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Change from Baseline to Day 30	n	77	39	33	149
		Mean (SD)	-1.5 (2.60)	-1.4 (2.10)	0.2 (3.02)	-1.1 (2.66)
		Median	-2.0	-1.0	0.0	-1.0
		Min, Max	-6, 5	-7, 4	-4, 9	-7, 9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Shift in Normality from Baseline to Day 30	Normal to Normal - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)
		Normal to High, NCS - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Shift in Toxicity from Baseline to Day 30	Blood Urea Nitrogen				
		0 to 0 - n (%)	77 (96.3)	39 (95.1)	31 (79.5)	147 (91.9)
		0 to 1 - n (%)	0	0	2 (5.1)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Day 60	n	74	37	31	142
		Mean (SD)	13.3 (2.72)	12.9 (2.57)	13.5 (3.20)	13.3 (2.78)
		Median	13.0	12.0	14.0	13.0
		Min, Max	7, 19	8, 21	6, 19	6, 21
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Day 60	Blood Urea Nitrogen				
		Grade 0 - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	-0.9 (2.82)	-1.4 (2.05)	-0.6 (1.89)	-1.0 (2.46)
		Median	0.0	-2.0	-1.0	-1.0
		Min, Max	-10, 5	-5, 5	-4, 3	-10, 5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Shift in Toxicity from Baseline to Day 60	Blood Urea Nitrogen 0 to 0 - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Day 91/Discharge n Ambulatory		74	36	33	143
		Mean (SD)	13.1 (2.87)	12.4 (2.55)	12.8 (2.63)	12.9 (2.74)
		Median	13.0	12.0	12.0	13.0
		Min, Max	7, 20	6, 19	7, 18	6, 20
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Day 91/Discharge Ambulatory	Blood Urea Nitrogen Grade 0 - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Change from Baseline to Day 91/Discharge Ambulatory	n	74	36	33	143
		Mean (SD)	-1.1 (2.76)	-1.7 (2.26)	-1.4 (1.72)	-1.3 (2.43)
		Median	-1.0	-2.0	-1.0	-1.0
		Min, Max	-7, 6	-7, 4	-5, 3	-7, 6

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Normal - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Blood urea nitrogen (mg/dL) [4-24]	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	Blood Urea Nitrogen 0 to 0 - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Baseline	n	80	41	39	160
		Mean (SD)	135.8 (69.59)	129.6 (45.39)	124.6 (43.89)	131.5 (58.37)
		Median	121.0	118.0	114.0	117.5
		Min, Max	54, 438	68, 248	68, 238	54, 438
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	75 (93.8)	37 (90.2)	38 (97.4)	150 (93.8)
		High value - n (%)	5 (6.3)	4 (9.8)	1 (2.6)	10 (6.3)
		Abnormal CS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS - n (%)	4 (5.0)	4 (9.8)	1 (2.6)	9 (5.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Baseline	Hypertriglyceridemia				
		Grade 0 - n (%)	56 (70.0)	26 (63.4)	29 (74.4)	111 (69.4)
		Grade 1 - n (%)	20 (25.0)	15 (36.6)	10 (25.6)	45 (28.1)
		Grade 2 - n (%)	4 (5.0)	0	0	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	124.8 (71.83)	115.2 (50.44)	124.6 (57.53)	122.3 (63.56)
		Median	95.0	97.5	120.0	98.0
		Min, Max	60, 430	60, 232	47, 302	47, 430
		Low value - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal value - n (%)	77 (96.3)	38 (92.7)	33 (84.6)	148 (92.5)
		High value - n (%)	3 (3.8)	2 (4.9)	1 (2.6)	6 (3.8)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	2 (4.9)	2 (5.1)	7 (4.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Day 6/Discharge Confinement	Hypertriglyceridemia				
		Grade 0 - n (%)	62 (77.5)	29 (70.7)	23 (59.0)	114 (71.3)
		Grade 1 - n (%)	15 (18.8)	11 (26.8)	11 (28.2)	37 (23.1)
		Grade 2 - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US Program: t_labchem.sas Status: Final

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	-11.0 (38.34)	-13.4 (29.35)	0.3 (43.61)	-9.1 (37.67)
		Median	-8.0	-12.5	-14.0	-12.0
		Min, Max	-165, 134	-98, 46	-103, 90	-165, 134

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Low, NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal to Normal - n (%)	75 (93.8)	36 (87.8)	32 (82.1)	143 (89.4)
		Normal to High, NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		High, NCS to Normal - n (%)	2 (2.5)	2 (4.9)	1 (2.6)	5 (3.1)
		High, NCS to High, NCS - n (%)	2 (2.5)	2 (4.9)	0	4 (2.5)
		High, CS to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	Hypertriglyceridemia				
		0 to 0 - n (%)	54 (67.5)	25 (61.0)	21 (53.8)	100 (62.5)
		0 to 1 - n (%)	2 (2.5)	1 (2.4)	6 (15.4)	9 (5.6)
		1 to 0 - n (%)	7 (8.8)	4 (9.8)	2 (5.1)	13 (8.1)
		1 to 1 - n (%)	12 (15.0)	10 (24.4)	5 (12.8)	27 (16.9)
		1 to 2 - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		2 to 0 - n (%)	1 (1.3)	0	0	1 (0.6)
		2 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)
		2 to 2 - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Day 30	n	77	39	33	149
		Mean (SD)	143.5 (93.18)	129.2 (73.89)	140.6 (55.97)	139.1 (81.08)
		Median	119.0	108.0	134.0	118.0
		Min, Max	47, 676	50, 364	48, 276	47, 676
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	71 (88.8)	34 (82.9)	32 (82.1)	137 (85.6)
		High value - n (%)	6 (7.5)	5 (12.2)	1 (2.6)	12 (7.5)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	6 (7.5)	5 (12.2)	1 (2.6)	12 (7.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Day 30	Hypertriglyceridemia				
		Grade 0 - n (%)	55 (68.8)	28 (68.3)	20 (51.3)	103 (64.4)
		Grade 1 - n (%)	17 (21.3)	8 (19.5)	13 (33.3)	38 (23.8)
		Grade 2 - n (%)	4 (5.0)	3 (7.3)	0	7 (4.4)
		Grade 3 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Change from Baseline to Day 30	n	77	39	33	149
		Mean (SD)	4.9 (48.34)	1.0 (51.36)	19.5 (40.32)	7.1 (47.70)
		Median	-3.0	-3.0	17.0	-2.0
		Min, Max	-85, 283	-124, 154	-54, 128	-124, 283

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Shift in Normality from Baseline to Day 30	Normal to Normal - n (%)	70 (87.5)	33 (80.5)	31 (79.5)	134 (83.8)
		Normal to High, NCS - n (%)	2 (2.5)	2 (4.9)	1 (2.6)	5 (3.1)
		High, NCS to Normal - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		High, NCS to High, NCS - n (%)	3 (3.8)	3 (7.3)	0	6 (3.8)
		High, CS to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Shift in Toxicity from Baseline to Day 30	Hypertriglyceridemia				
		0 to 0 - n (%)	49 (61.3)	23 (56.1)	19 (48.7)	91 (56.9)
		0 to 1 - n (%)	4 (5.0)	2 (4.9)	7 (17.9)	13 (8.1)
		1 to 0 - n (%)	6 (7.5)	5 (12.2)	1 (2.6)	12 (7.5)
		1 to 1 - n (%)	13 (16.3)	6 (14.6)	6 (15.4)	25 (15.6)
		1 to 2 - n (%)	1 (1.3)	3 (7.3)	0	4 (2.5)
		2 to 2 - n (%)	3 (3.8)	0	0	3 (1.9)
		2 to 3 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Day 60	n	74	37	31	142
		Mean (SD)	141.5 (76.85)	140.4 (54.89)	129.8 (47.62)	138.6 (65.81)
		Median	120.0	128.0	127.0	124.0
		Min, Max	49, 432	71, 315	43, 240	43, 432
		Low value - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal value - n (%)	69 (86.3)	35 (85.4)	29 (74.4)	133 (83.1)
		High value - n (%)	5 (6.3)	2 (4.9)	1 (2.6)	8 (5.0)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	5 (6.3)	2 (4.9)	2 (5.1)	9 (5.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Day 60	Hypertriglyceridemia				
		Grade 0 - n (%)	48 (60.0)	24 (58.5)	22 (56.4)	94 (58.8)
		Grade 1 - n (%)	21 (26.3)	12 (29.3)	9 (23.1)	42 (26.3)
		Grade 2 - n (%)	5 (6.3)	1 (2.4)	0	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	4.3 (46.00)	14.6 (32.07)	8.5 (25.90)	7.9 (38.99)
		Median	5.5	10.0	6.0	8.0
		Min, Max	-139, 211	-92, 74	-68, 70	-139, 211

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Shift in Normality from Baseline to Day 60	Normal to Low, NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal to Normal - n (%)	68 (85.0)	35 (85.4)	28 (71.8)	131 (81.9)
		Normal to High, NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		High, NCS to Normal - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		High, NCS to High, NCS - n (%)	3 (3.8)	2 (4.9)	0	5 (3.1)
		High, CS to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Shift in Toxicity from Baseline to Day 60	Hypertriglyceridemia				
		0 to 0 - n (%)	44 (55.0)	22 (53.7)	21 (53.8)	87 (54.4)
		0 to 1 - n (%)	7 (8.8)	4 (9.8)	3 (7.7)	14 (8.8)
		1 to 0 - n (%)	4 (5.0)	2 (4.9)	1 (2.6)	7 (4.4)
		1 to 1 - n (%)	13 (16.3)	8 (19.5)	6 (15.4)	27 (16.9)
		1 to 2 - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		2 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)
		2 to 2 - n (%)	3 (3.8)	0	0	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Day 91/Discharge n Ambulatory		74	36	33	143
		Mean (SD)	137.5 (72.22)	130.3 (59.69)	127.6 (59.77)	133.4 (66.21)
		Median	117.5	115.0	122.0	117.0
		Min, Max	55, 397	58, 369	48, 320	48, 397
		Low value - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal value - n (%)	67 (83.8)	32 (78.0)	30 (76.9)	129 (80.6)
		High value - n (%)	7 (8.8)	4 (9.8)	2 (5.1)	13 (8.1)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	7 (8.8)	4 (9.8)	3 (7.7)	14 (8.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Day 91/Discharge Ambulatory	Hypertriglyceridemia				
		Grade 0 - n (%)	49 (61.3)	24 (58.5)	26 (66.7)	99 (61.9)
		Grade 1 - n (%)	22 (27.5)	11 (26.8)	6 (15.4)	39 (24.4)
		Grade 2 - n (%)	3 (3.8)	1 (2.4)	1 (2.6)	5 (3.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Change from Baseline to Day 91/Discharge Ambulatory	n	74	36	33	143
		Mean (SD)	0.9 (37.64)	5.9 (30.80)	6.5 (44.61)	3.4 (37.65)
		Median	-1.5	2.5	3.0	1.0
		Min, Max	-78, 138	-50, 121	-64, 181	-78, 181

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Low, NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal to Normal - n (%)	67 (83.8)	32 (78.0)	29 (74.4)	128 (80.0)
		Normal to High, NCS - n (%)	2 (2.5)	2 (4.9)	2 (5.1)	6 (3.8)
		High, NCS to Normal - n (%)	0	0	1 (2.6)	1 (0.6)
		High, NCS to High, NCS - n (%)	4 (5.0)	2 (4.9)	0	6 (3.8)
		High, CS to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Triglycerides (mg/dL)	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	Hypertriglyceridemia				
		0 to 0 - n (%)	45 (56.3)	21 (51.2)	24 (61.5)	90 (56.3)
		0 to 1 - n (%)	6 (7.5)	5 (12.2)	1 (2.6)	12 (7.5)
		0 to 2 - n (%)	0	0	1 (2.6)	1 (0.6)
		1 to 0 - n (%)	4 (5.0)	3 (7.3)	2 (5.1)	9 (5.6)
		1 to 1 - n (%)	14 (17.5)	6 (14.6)	5 (12.8)	25 (15.6)
		1 to 2 - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		2 to 1 - n (%)	2 (2.5)	0	0	2 (1.3)
		2 to 2 - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Baseline	n	80	41	39	160
		Mean (SD)	189.9 (39.47)	192.9 (36.05)	193.8 (37.37)	191.6 (37.92)
		Median	189.0	194.0	188.0	189.0
		Min, Max	90, 304	129, 273	139, 266	90, 304
		Low value - n (%)	11 (13.8)	3 (7.3)	4 (10.3)	18 (11.3)
		Normal value - n (%)	65 (81.3)	36 (87.8)	35 (89.7)	136 (85.0)
		High value - n (%)	4 (5.0)	2 (4.9)	0	6 (3.8)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	15 (18.8)	5 (12.2)	4 (10.3)	24 (15.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Baseline	Cholesterol high				
		Grade 0 - n (%)	76 (95.0)	39 (95.1)	39 (100)	154 (96.3)
		Grade 1 - n (%)	3 (3.8)	2 (4.9)	0	5 (3.1)
		Grade 2 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	176.9 (35.00)	174.0 (33.50)	187.5 (39.94)	178.5 (35.91)
		Median	179.0	177.5	184.0	180.0
		Min, Max	77, 278	109, 249	110, 274	77, 278
		Low value - n (%)	17 (21.3)	7 (17.1)	6 (15.4)	30 (18.8)
		Normal value - n (%)	62 (77.5)	32 (78.0)	29 (74.4)	123 (76.9)
		High value - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	18 (22.5)	8 (19.5)	6 (15.4)	32 (20.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Day 6/Discharge Confinement	Cholesterol high				
		Grade 0 - n (%)	79 (98.8)	39 (95.1)	35 (89.7)	153 (95.6)
		Grade 1 - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	-13.0 (19.00)	-19.4 (17.07)	-8.5 (19.32)	-13.6 (18.87)
		Median	-13.0	-17.5	-8.0	-13.0
		Min, Max	-75, 31	-59, 25	-58, 24	-75, 31

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Low, NCS to Low, NCS - n (%)	11 (13.8)	3 (7.3)	3 (7.7)	17 (10.6)
		Normal to Low, NCS - n (%)	6 (7.5)	4 (9.8)	3 (7.7)	13 (8.1)
		Normal to Normal - n (%)	59 (73.8)	31 (75.6)	29 (74.4)	119 (74.4)
		High, NCS to Normal - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		High, NCS to High, NCS - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	Cholesterol high				
		0 to 0 - n (%)	76 (95.0)	38 (92.7)	35 (89.7)	149 (93.1)
		1 to 0 - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		1 to 1 - n (%)	0	1 (2.4)	0	1 (0.6)
		2 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Day 30	n	77	39	33	149
		Mean (SD)	183.1 (41.18)	186.2 (38.22)	191.7 (35.49)	185.8 (39.11)
		Median	179.0	185.0	195.0	185.0
		Min, Max	82, 307	114, 287	121, 262	82, 307
		Low value - n (%)	12 (15.0)	4 (9.8)	3 (7.7)	19 (11.9)
		Normal value - n (%)	61 (76.3)	33 (80.5)	30 (76.9)	124 (77.5)
		High value - n (%)	4 (5.0)	2 (4.9)	0	6 (3.8)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	16 (20.0)	6 (14.6)	3 (7.7)	25 (15.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Day 30	Cholesterol high				
		Grade 0 - n (%)	73 (91.3)	37 (90.2)	33 (84.6)	143 (89.4)
		Grade 1 - n (%)	3 (3.8)	2 (4.9)	0	5 (3.1)
		Grade 2 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Change from Baseline to Day 30	n	77	39	33	149
		Mean (SD)	-7.9 (24.60)	-6.2 (21.60)	-4.0 (20.51)	-6.6 (22.89)
		Median	-5.0	-7.0	-7.0	-6.0
		Min, Max	-83, 44	-63, 36	-47, 33	-83, 44

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Shift in Normality from Baseline to Day 30	Low, NCS to Low, NCS - n (%)	7 (8.8)	1 (2.4)	2 (5.1)	10 (6.3)
		Low, NCS to Normal - n (%)	3 (3.8)	2 (4.9)	1 (2.6)	6 (3.8)
		Normal to Low, NCS - n (%)	5 (6.3)	3 (7.3)	1 (2.6)	9 (5.6)
		Normal to Normal - n (%)	56 (70.0)	30 (73.2)	29 (74.4)	115 (71.9)
		Normal to High, NCS - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		High, NCS to Normal - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		High, NCS to High, NCS - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Shift in Toxicity from Baseline to Day 30	Cholesterol high				
		0 to 0 - n (%)	71 (88.8)	36 (87.8)	33 (84.6)	140 (87.5)
		0 to 1 - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		1 to 0 - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		1 to 1 - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		2 to 2 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Day 60	n	74	37	31	142
		Mean (SD)	180.1 (35.95)	184.8 (35.76)	190.3 (40.62)	183.6 (36.92)
		Median	177.5	184.0	196.0	183.5
		Min, Max	101, 294	116, 258	115, 275	101, 294
		Low value - n (%)	15 (18.8)	7 (17.1)	4 (10.3)	26 (16.3)
		Normal value - n (%)	56 (70.0)	29 (70.7)	27 (69.2)	112 (70.0)
		High value - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	18 (22.5)	8 (19.5)	4 (10.3)	30 (18.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Day 60	Cholesterol high				
		Grade 0 - n (%)	71 (88.8)	36 (87.8)	31 (79.5)	138 (86.3)
		Grade 1 - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	-9.9 (25.62)	-7.3 (20.97)	-4.2 (21.42)	-8.0 (23.56)
		Median	-9.5	-4.0	-3.0	-6.5
		Min, Max	-85, 41	-70, 23	-42, 46	-85, 46

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Shift in Normality from Baseline to Day 60	Low, NCS to Low, NCS - n (%)	8 (10.0)	3 (7.3)	2 (5.1)	13 (8.1)
		Low, NCS to Normal - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)
		Normal to Low, NCS - n (%)	7 (8.8)	4 (9.8)	2 (5.1)	13 (8.1)
		Normal to Normal - n (%)	51 (63.8)	28 (68.3)	26 (66.7)	105 (65.6)
		Normal to High, NCS - n (%)	2 (2.5)	0	0	2 (1.3)
		High, NCS to Normal - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		High, NCS to High, NCS - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Shift in Toxicity from Baseline to Day 60	Cholesterol high				
		0 to 0 - n (%)	68 (85.0)	35 (85.4)	31 (79.5)	134 (83.8)
		0 to 1 - n (%)	2 (2.5)	0	0	2 (1.3)
		1 to 0 - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		1 to 1 - n (%)	0	1 (2.4)	0	1 (0.6)
		2 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Day 91/Discharge n Ambulatory		74	36	33	143
		Mean (SD)	186.5 (37.91)	194.1 (40.89)	196.7 (46.30)	190.8 (40.67)
		Median	186.0	185.0	207.0	186.0
		Min, Max	111, 310	120, 292	122, 305	111, 310
		Low value - n (%)	11 (13.8)	3 (7.3)	4 (10.3)	18 (11.3)
		Normal value - n (%)	61 (76.3)	29 (70.7)	28 (71.8)	118 (73.8)
		High value - n (%)	2 (2.5)	4 (9.8)	1 (2.6)	7 (4.4)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	13 (16.3)	7 (17.1)	5 (12.8)	25 (15.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Day 91/Discharge	Cholesterol high				
	Ambulatory					
		Grade 0 - n (%)	72 (90.0)	32 (78.0)	32 (82.1)	136 (85.0)
		Grade 1 - n (%)	1 (1.3)	4 (9.8)	0	5 (3.1)
		Grade 2 - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Change from Baseline to Day 91/Discharge Ambulatory	n	74	36	33	143
		Mean (SD)	-2.6 (23.38)	0.6 (18.18)	1.0 (22.28)	-1.0 (21.85)
		Median	-2.5	2.0	1.0	0.0
		Min, Max	-51, 46	-37, 52	-39, 69	-51, 69

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Low, NCS to Low, NCS - n (%)	7 (8.8)	2 (4.9)	3 (7.7)	12 (7.5)
		Low, NCS to Normal - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		Normal to Low, NCS - n (%)	4 (5.0)	1 (2.4)	1 (2.6)	6 (3.8)
		Normal to Normal - n (%)	55 (68.8)	27 (65.9)	28 (71.8)	110 (68.8)
		Normal to High, NCS - n (%)	1 (1.3)	3 (7.3)	1 (2.6)	5 (3.1)
		High, NCS to Normal - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		High, NCS to High, NCS - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Cholesterol (mg/dL)	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	Cholesterol high				
		0 to 0 - n (%)	69 (86.3)	31 (75.6)	32 (82.1)	132 (82.5)
		0 to 1 - n (%)	1 (1.3)	3 (7.3)	0	4 (2.5)
		0 to 2 - n (%)	0	0	1 (2.6)	1 (0.6)
		1 to 0 - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		1 to 1 - n (%)	0	1 (2.4)	0	1 (0.6)
		2 to 2 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Baseline	n	80	41	39	160
		Mean (SD)	41.0 (3.24)	41.5 (2.60)	41.0 (3.73)	41.1 (3.21)
		Median	41.0	41.0	41.0	41.0
		Min, Max	34, 50	36, 47	34, 48	34, 50
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	79 (98.8)	41 (100)	39 (100)	159 (99.4)
		High value - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Baseline	Hypoalbuminemia Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	160 (100)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	41.8 (2.89)	41.8 (2.67)	41.6 (3.06)	41.8 (2.86)
		Median	42.0	42.0	42.0	42.0
		Min, Max	35, 49	36, 49	35, 48	35, 49
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Day 6/Discharge	Hypoalbuminemia				
	Confinement	Grade 0 - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	0.9 (2.10)	0.3 (2.03)	0.6 (2.40)	0.7 (2.15)
		Median	1.0	0.0	1.0	1.0
		Min, Max	-6, 5	-4, 5	-6, 5	-6, 5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		High, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	Hypoalbuminemia 0 to 0 - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Day 30	n	77	39	33	149
		Mean (SD)	40.1 (3.17)	40.8 (2.99)	40.3 (3.10)	40.4 (3.10)
		Median	40.0	41.0	40.0	40.0
		Min, Max	33, 50	34, 47	34, 48	33, 50
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	76 (95.0)	39 (95.1)	33 (84.6)	148 (92.5)
		High value - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Day 30	Hypoalbuminemia Grade 0 - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Change from Baseline to Day 30	n	77	39	33	149
		Mean (SD)	-0.9 (2.66)	-0.6 (2.33)	-0.5 (2.70)	-0.8 (2.58)
		Median	-1.0	0.0	-1.0	-1.0
		Min, Max	-7, 6	-6, 4	-6, 5	-7, 6

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Shift in Normality from Baseline to Day 30	Normal to Normal - n (%)	75 (93.8)	39 (95.1)	33 (84.6)	147 (91.9)
		Normal to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Shift in Toxicity from Baseline to Day 30	Hypoalbuminemia 0 to 0 - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Day 60	n	74	37	31	142
		Mean (SD)	40.4 (3.14)	40.4 (3.08)	39.8 (3.68)	40.3 (3.24)
		Median	40.0	41.0	39.0	40.0
		Min, Max	34, 51	33, 46	33, 47	33, 51
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	73 (91.3)	37 (90.2)	31 (79.5)	141 (88.1)
		High value - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Day 60	Hypoalbuminemia Grade 0 - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	-0.6 (3.00)	-1.0 (2.79)	-1.0 (3.55)	-0.8 (3.06)
		Median	0.0	0.0	0.0	0.0
		Min, Max	-7, 8	-8, 4	-9, 6	-9, 8

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	72 (90.0)	37 (90.2)	31 (79.5)	140 (87.5)
		Normal to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Shift in Toxicity from Baseline to Day 60	Hypoalbuminemia 0 to 0 - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Day 91/Discharge n Ambulatory		74	36	33	143
		Mean (SD)	42.8 (3.00)	42.7 (3.04)	42.2 (3.06)	42.6 (3.01)
		Median	42.0	42.5	42.0	42.0
		Min, Max	36, 51	37, 50	34, 47	34, 51
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	73 (91.3)	35 (85.4)	33 (84.6)	141 (88.1)
		High value - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49] Day 91/Discharge Hypoalbuminemia Ambulatory						
		Grade 0 - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Change from Baseline to Day 91/Discharge Ambulatory	n	74	36	33	143
		Mean (SD)	1.8 (2.94)	1.3 (3.01)	1.3 (3.24)	1.6 (3.02)
		Median	2.0	1.0	2.0	2.0
		Min, Max	-5, 8	-7, 9	-5, 9	-7, 9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Normal - n (%)	72 (90.0)	35 (85.4)	33 (84.6)	140 (87.5)
		Normal to High, NCS - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		High, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Albumin (g/L) [33-49]	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	Hypoalbuminemia 0 to 0 - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Baseline	n	80	41	39	160
		Mean (SD)	140.3 (1.87)	140.3 (2.30)	140.2 (1.80)	140.3 (1.96)
		Median	140.0	140.0	140.0	140.0
		Min, Max	136, 147	133, 146	137, 144	133, 147
		Low value - n (%)	0	1 (2.4)	0	1 (0.6)
		Normal value - n (%)	80 (100)	40 (97.6)	39 (100)	159 (99.4)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Baseline	Hypernatremia				
		Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	160 (100)
		Hyponatremia				
		Grade 0 - n (%)	80 (100)	40 (97.6)	39 (100)	159 (99.4)
		Grade 1 - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	140.2 (1.77)	140.2 (2.23)	139.8 (1.85)	140.1 (1.91)
		Median	140.0	140.0	140.0	140.0
		Min, Max	136, 145	135, 148	136, 144	135, 148
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	39 (95.1)	35 (89.7)	154 (96.3)
		High value - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Day 6/Discharge Confinement	Hypernatremia				
		Grade 0 - n (%)	80 (100)	39 (95.1)	35 (89.7)	154 (96.3)
		Grade 1 - n (%)	0	1 (2.4)	0	1 (0.6)
		Hyponatremia				
		Grade 0 - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	-0.1 (2.06)	-0.2 (2.51)	-0.5 (1.83)	-0.2 (2.13)
		Median	0.0	-0.5	0.0	0.0
		Min, Max	-6, 4	-7, 7	-4, 3	-7, 7

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Low, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)
		Normal to Normal - n (%)	80 (100)	38 (92.7)	35 (89.7)	153 (95.6)
		Normal to High, NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	Hypernatremia				
		0 to 0 - n (%)	80 (100)	39 (95.1)	35 (89.7)	154 (96.3)
		0 to 1 - n (%)	0	1 (2.4)	0	1 (0.6)
		Hyponatremia				
		0 to 0 - n (%)	80 (100)	39 (95.1)	35 (89.7)	154 (96.3)
		1 to 0 - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Day 30	n	77	39	33	149
		Mean (SD)	140.9 (2.06)	141.1 (2.00)	140.3 (1.90)	140.8 (2.02)
		Median	141.0	141.0	141.0	141.0
		Min, Max	137, 148	137, 145	136, 144	136, 148
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	76 (95.0)	39 (95.1)	33 (84.6)	148 (92.5)
		High value - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Day 30	Hypernatremia				
		Grade 0 - n (%)	76 (95.0)	39 (95.1)	33 (84.6)	148 (92.5)
		Grade 1 - n (%)	1 (1.3)	0	0	1 (0.6)
		Hyponatremia				
		Grade 0 - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Change from Baseline to Day 30	n	77	39	33	149
		Mean (SD)	0.5 (2.15)	0.7 (2.72)	0.1 (2.15)	0.5 (2.31)
		Median	0.0	1.0	0.0	0.0
		Min, Max	-3, 6	-5, 9	-5, 5	-5, 9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Shift in Normality from Baseline to Day 30	Low, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)
		Normal to Normal - n (%)	76 (95.0)	38 (92.7)	33 (84.6)	147 (91.9)
		Normal to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Shift in Toxicity from Baseline to Day 30	Hypernatremia				
		0 to 0 - n (%)	76 (95.0)	39 (95.1)	33 (84.6)	148 (92.5)
		0 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)
		Hyponatremia				
		0 to 0 - n (%)	77 (96.3)	38 (92.7)	33 (84.6)	148 (92.5)
		1 to 0 - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Day 60	n	74	37	31	142
		Mean (SD)	140.5 (1.89)	140.6 (2.31)	140.3 (1.98)	140.5 (2.01)
		Median	141.0	140.0	141.0	140.0
		Min, Max	136, 145	137, 147	136, 145	136, 147
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	36 (87.8)	31 (79.5)	141 (88.1)
		High value - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Day 60	Hypernatremia				
		Grade 0 - n (%)	74 (92.5)	36 (87.8)	31 (79.5)	141 (88.1)
		Grade 1 - n (%)	0	1 (2.4)	0	1 (0.6)
		Hyponatremia				
		Grade 0 - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	0.1 (2.18)	0.4 (3.26)	0.1 (2.22)	0.2 (2.50)
		Median	0.0	0.0	0.0	0.0
		Min, Max	-7, 5	-8, 13	-5, 5	-8, 13

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Shift in Normality from Baseline to Day 60	Low, NCS to High, NCS - n (%)	0	1 (2.4)	0	1 (0.6)
		Normal to Normal - n (%)	74 (92.5)	36 (87.8)	31 (79.5)	141 (88.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Shift in Toxicity from Baseline to Day 60	Hypernatremia				
		0 to 0 - n (%)	74 (92.5)	36 (87.8)	31 (79.5)	141 (88.1)
		0 to 1 - n (%)	0	1 (2.4)	0	1 (0.6)
		Hyponatremia				
		0 to 0 - n (%)	74 (92.5)	36 (87.8)	31 (79.5)	141 (88.1)
		1 to 0 - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Day 91/Discharge n Ambulatory		74	36	33	143
		Mean (SD)	139.6 (1.89)	139.2 (2.00)	139.6 (2.02)	139.5 (1.94)
		Median	139.5	139.0	140.0	139.0
		Min, Max	135, 146	136, 143	136, 144	135, 146
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Day 91/Discharge Ambulatory	Grade 0 - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)
		Hyponatremia				
		Grade 0 - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Change from Baseline to Day 91/Discharge Ambulatory	n	74	36	33	143
		Mean (SD)	-0.9 (2.04)	-1.0 (2.04)	-0.6 (1.70)	-0.8 (1.96)
		Median	0.0	-1.0	-1.0	-1.0
		Min, Max	-9, 3	-6, 4	-3, 3	-9, 4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Low, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)
		Normal to Normal - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Sodium (mmol/L)	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	Hypernatremia				
		0 to 0 - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)
		Hyponatremia				
		0 to 0 - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)
		1 to 0 - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Baseline	n	80	41	39	160
		Mean (SD)	4.28 (0.333)	4.27 (0.345)	4.14 (0.333)	4.24 (0.339)
		Median	4.30	4.30	4.20	4.20
		Min, Max	3.6, 5.3	3.5, 5.0	3.4, 4.9	3.4, 5.3
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	160 (100)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Baseline	Hyperkalemia				
		Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	160 (100)
		Hypokalemia				
		Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	160 (100)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	4.28 (0.314)	4.31 (0.407)	4.27 (0.373)	4.29 (0.352)
		Median	4.30	4.30	4.20	4.30
		Min, Max	3.5, 5.2	3.8, 6.0	3.5, 5.3	3.5, 6.0
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	39 (95.1)	35 (89.7)	154 (96.3)
		High value - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Day 6/Discharge Confinement	Hyperkalemia				
		Grade 0 - n (%)	80 (100)	39 (95.1)	35 (89.7)	154 (96.3)
		Grade 2 - n (%)	0	1 (2.4)	0	1 (0.6)
		Hypokalemia				
		Grade 0 - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	-0.01 (0.341)	0.04 (0.448)	0.10 (0.425)	0.03 (0.390)
		Median	0.00	-0.05	0.10	0.00
		Min, Max	-0.8, 1.1	-0.9, 1.6	-0.6, 1.0	-0.9, 1.6

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Normal - n (%)	80 (100)	39 (95.1)	35 (89.7)	154 (96.3)
		Normal to High, NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	Hyperkalemia				
		0 to 0 - n (%)	80 (100)	39 (95.1)	35 (89.7)	154 (96.3)
		0 to 2 - n (%)	0	1 (2.4)	0	1 (0.6)
		Hypokalemia				
		0 to 0 - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Day 30	n	77	39	33	149
		Mean (SD)	4.35 (0.363)	4.35 (0.378)	4.37 (0.298)	4.36 (0.352)
		Median	4.30	4.30	4.30	4.30
		Min, Max	3.7, 5.6	3.6, 5.2	3.8, 4.9	3.6, 5.6
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	75 (93.8)	39 (95.1)	33 (84.6)	147 (91.9)
		High value - n (%)	2 (2.5)	0	0	2 (1.3)
		Abnormal CS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Day 30	Hyperkalemia				
		Grade 0 - n (%)	75 (93.8)	39 (95.1)	33 (84.6)	147 (91.9)
		Grade 1 - n (%)	1 (1.3)	0	0	1 (0.6)
		Grade 2 - n (%)	1 (1.3)	0	0	1 (0.6)
		Hypokalemia				
		Grade 0 - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Change from Baseline to Day 30	n	77	39	33	149
		Mean (SD)	0.08 (0.380)	0.08 (0.450)	0.20 (0.385)	0.10 (0.401)
		Median	0.10	0.10	0.20	0.10
		Min, Max	-0.9, 1.1	-1.0, 1.0	-0.5, 1.0	-1.0, 1.1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Shift in Normality from Baseline to Day 30	Normal to Normal - n (%)	75 (93.8)	39 (95.1)	33 (84.6)	147 (91.9)
		Normal to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to High, CS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Shift in Toxicity from Baseline to Day 30	Hyperkalemia				
		0 to 0 - n (%)	75 (93.8)	39 (95.1)	33 (84.6)	147 (91.9)
		0 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)
		0 to 2 - n (%)	1 (1.3)	0	0	1 (0.6)
		Hypokalemia				
		0 to 0 - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Day 60	n	74	37	31	142
		Mean (SD)	4.26 (0.282)	4.24 (0.321)	4.33 (0.308)	4.27 (0.298)
		Median	4.30	4.30	4.30	4.30
		Min, Max	3.4, 5.0	3.7, 5.0	3.6, 5.0	3.4, 5.0
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Day 60	Hyperkalemia				
		Grade 0 - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)
		Hypokalemia				
		Grade 0 - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	0.00 (0.384)	-0.04 (0.410)	0.15 (0.429)	0.02 (0.404)
		Median	0.00	0.00	0.10	0.00
		Min, Max	-1.3, 1.1	-0.9, 0.9	-0.7, 1.5	-1.3, 1.5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Shift in Toxicity from Baseline to Day 60	Hyperkalemia				
		0 to 0 - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)
		Hypokalemia				
		0 to 0 - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Day 91/Discharge n Ambulatory		74	36	33	143
		Mean (SD)	4.20 (0.418)	4.19 (0.373)	4.29 (0.357)	4.22 (0.393)
		Median	4.25	4.20	4.30	4.20
		Min, Max	3.2, 5.3	3.7, 5.1	3.4, 5.1	3.2, 5.3
		Low value - n (%)	2 (2.5)	0	0	2 (1.3)
		Normal value - n (%)	72 (90.0)	36 (87.8)	33 (84.6)	141 (88.1)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Day 91/Discharge Ambulatory	Hyperkalemia				
		Grade 0 - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)
		Hypokalemia				
		Grade 0 - n (%)	72 (90.0)	36 (87.8)	33 (84.6)	141 (88.1)
		Grade 1 - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Change from Baseline to Day 91/Discharge Ambulatory	n	74	36	33	143
		Mean (SD)	-0.07 (0.435)	-0.09 (0.419)	0.12 (0.359)	-0.03 (0.420)
		Median	0.00	-0.10	0.10	0.00
		Min, Max	-1.4, 0.9	-0.8, 0.9	-0.6, 0.9	-1.4, 0.9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, CS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	72 (90.0)	36 (87.8)	33 (84.6)	141 (88.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Potassium (mmol/L) [3.4-5.4]	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	Hyperkalemia				
		0 to 0 - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)
		Hypokalemia				
		0 to 0 - n (%)	72 (90.0)	36 (87.8)	33 (84.6)	141 (88.1)
		0 to 1 - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ldl cholesterol (mg/dL)	Baseline	n	80	41	39	160
		Mean (SD)	116.8 (35.33)	120.8 (33.00)	124.8 (35.74)	119.8 (34.79)
		Median	113.5	115.0	117.0	114.0
		Min, Max	30, 204	62, 199	71, 197	30, 204
		Low value - n (%)	11 (13.8)	1 (2.4)	2 (5.1)	14 (8.8)
		Normal value - n (%)	66 (82.5)	37 (90.2)	36 (92.3)	139 (86.9)
		High value - n (%)	3 (3.8)	3 (7.3)	1 (2.6)	7 (4.4)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ldl cholesterol (mg/dL)	Day 30	n	76	39	33	148
		Mean (SD)	107.5 (34.77)	111.8 (30.38)	116.8 (32.38)	110.7 (33.13)
		Median	106.0	110.0	118.0	108.5
		Min, Max	24, 209	61, 175	55, 185	24, 209
		Low value - n (%)	14 (17.5)	4 (9.8)	4 (10.3)	22 (13.8)
		Normal value - n (%)	60 (75.0)	34 (82.9)	29 (74.4)	123 (76.9)
		High value - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ldl cholesterol (mg/dL)	Change from Baseline to Day 30	n	76	39	33	148
		Mean (SD)	-10.1 (19.05)	-9.2 (16.77)	-9.0 (25.47)	-9.6 (19.98)
		Median	-11.0	-11.0	-9.0	-10.0
		Min, Max	-49, 32	-51, 27	-121, 38	-121, 38

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US

Program: t_labchem.sas

Status: Final

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ldl cholesterol (mg/dL)	Shift in Normality from Baseline to Day 30	Low to Low - n (%)	7 (8.8)	0	2 (5.1)	9 (5.6)
		Low to Normal - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		Normal to Low - n (%)	7 (8.8)	4 (9.8)	1 (2.6)	12 (7.5)
		Normal to Normal - n (%)	56 (70.0)	31 (75.6)	29 (74.4)	116 (72.5)
		High to Low - n (%)	0	0	1 (2.6)	1 (0.6)
		High to Normal - n (%)	1 (1.3)	2 (4.9)	0	3 (1.9)
		High to High - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ldl cholesterol (mg/dL)	Day 60	n	74	37	31	142
		Mean (SD)	103.4 (30.50)	109.5 (31.69)	119.1 (35.93)	108.4 (32.42)
		Median	101.5	111.0	117.0	108.5
		Min, Max	35, 183	61, 180	52, 200	35, 200
		Low value - n (%)	14 (17.5)	6 (14.6)	4 (10.3)	24 (15.0)
		Normal value - n (%)	60 (75.0)	29 (70.7)	26 (66.7)	115 (71.9)
		High value - n (%)	0	2 (4.9)	1 (2.6)	3 (1.9)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ldl cholesterol (mg/dL)	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	-13.1 (22.46)	-11.0 (17.39)	-5.2 (25.98)	-10.8 (22.18)
		Median	-12.0	-8.0	-2.0	-8.0
		Min, Max	-102, 29	-74, 20	-109, 39	-109, 39

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ldl cholesterol (mg/dL)	Shift in Normality from Baseline to Day 60	Low to Low - n (%)	8 (10.0)	1 (2.4)	2 (5.1)	11 (6.9)
		Low to Normal - n (%)	2 (2.5)	0	0	2 (1.3)
		Normal to Low - n (%)	6 (7.5)	5 (12.2)	2 (5.1)	13 (8.1)
		Normal to Normal - n (%)	55 (68.8)	28 (68.3)	25 (64.1)	108 (67.5)
		Normal to High - n (%)	0	0	1 (2.6)	1 (0.6)
		High to Normal - n (%)	3 (3.8)	1 (2.4)	1 (2.6)	5 (3.1)
		High to High - n (%)	0	2 (4.9)	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ldl cholesterol (mg/dL)	Day 90	n	73	35	31	139
		Mean (SD)	109.7 (33.71)	116.8 (34.53)	121.9 (40.85)	114.2 (35.71)
		Median	112.0	113.0	123.0	113.0
		Min, Max	43, 217	62, 200	58, 209	43, 217
		Low value - n (%)	12 (15.0)	3 (7.3)	5 (12.8)	20 (12.5)
		Normal value - n (%)	60 (75.0)	30 (73.2)	24 (61.5)	114 (71.3)
		High value - n (%)	1 (1.3)	2 (4.9)	2 (5.1)	5 (3.1)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ldl cholesterol (mg/dL)	Change from Baseline to Day 90	n	73	35	31	139
		Mean (SD)	-6.1 (21.62)	-4.1 (14.26)	-2.4 (30.32)	-4.8 (22.27)
		Median	-5.0	-5.0	-1.0	-5.0
		Min, Max	-53, 37	-38, 38	-122, 78	-122, 78

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.6

Study ID: ZRHM-REXA-08-US

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**Table 15.2.6.16 Summary of Clinical Chemistry Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ldl cholesterol (mg/dL)	Shift in Normality from Baseline to Day 90	Low to Low - n (%)	7 (8.8)	0	2 (5.1)	9 (5.6)
		Low to Normal - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		Normal to Low - n (%)	5 (6.3)	3 (7.3)	2 (5.1)	10 (6.3)
		Normal to Normal - n (%)	55 (68.8)	28 (68.3)	24 (61.5)	107 (66.9)
		Normal to High - n (%)	0	0	2 (5.1)	2 (1.3)
		High to Low - n (%)	0	0	1 (2.6)	1 (0.6)
		High to Normal - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		High to High - n (%)	1 (1.3)	2 (4.9)	0	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Erythrocytes (T/L)	Screening	n	80	41	39	4	164
		Mean (SD)	4.749 (0.4235)	4.855 (0.3889)	4.861 (0.3866)	5.260 (0.3022)	4.815 (0.4105)
		Median	4.780	4.850	4.870	5.320	4.840
		Min, Max	3.92, 5.93	3.82, 5.62	4.13, 5.82	4.84, 5.56	3.82, 5.93
		Low value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Normal value - n (%)	78 (97.5)	40 (97.6)	38 (97.4)	3 (60.0)	159 (96.4)
		High value - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	1 (20.0)	4 (2.4)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	1 (2.4)	1 (2.6)	1 (20.0)	5 (3.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Erythrocytes (T/L)	Day 0	n	80	41	39	3	163
		Mean (SD)	4.871 (0.4238)	4.959 (0.4296)	5.010 (0.4279)	NC	4.932 (0.4298)
		Median	4.850	4.900	5.000	NC	4.900
		Min, Max	3.80, 5.90	3.80, 5.90	4.20, 6.30	NC	3.80, 6.30
		Low value - n (%)	4 (5.0)	1 (2.4)	1 (2.6)	0	6 (3.6)
		Normal value - n (%)	76 (95.0)	39 (95.1)	38 (97.4)	3 (60.0)	156 (94.5)
		High value - n (%)	0	1 (2.4)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	2 (4.9)	1 (2.6)	0	7 (4.2)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Hemoglobin (g/dL)	Screening	n	80	41	39	4	164
		Mean (SD)	14.37 (1.448)	14.79 (1.232)	14.57 (1.458)	15.63 (1.409)	14.55 (1.407)
		Median	14.50	15.00	14.80	15.80	14.70
		Min, Max	10.9, 17.5	11.4, 17.0	10.8, 18.2	14.0, 16.9	10.8, 18.2
		Low value - n (%)	2 (2.5)	0	1 (2.6)	0	3 (1.8)
		Normal value - n (%)	78 (97.5)	41 (100)	36 (92.3)	4 (80.0)	159 (96.4)
		High value - n (%)	0	0	2 (5.1)	0	2 (1.2)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	0	3 (7.7)	0	5 (3.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Hemoglobin (g/dL)	Screening	Hemoglobin decreased					
		Grade 0 - n (%)	71 (88.8)	38 (92.7)	33 (84.6)	4 (80.0)	146 (88.5)
		Grade 1 - n (%)	8 (10.0)	3 (7.3)	5 (12.8)	0	16 (9.7)
		Grade 2 - n (%)	1 (1.3)	0	1 (2.6)	0	2 (1.2)
		Hemoglobin increase					
		Grade 0 - n (%)	80 (100)	41 (100)	37 (94.9)	4 (80.0)	162 (98.2)
		Grade 1 - n (%)	0	0	2 (5.1)	0	2 (1.2)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Hemoglobin (g/dL) Day 0		n	80	41	39	3	163
		Mean (SD)	14.63 (1.445)	14.97 (1.217)	14.87 (1.487)	NC	14.80 (1.414)
		Median	14.90	15.10	15.10	NC	15.00
		Min, Max	11.2, 17.7	11.9, 17.5	11.1, 19.2	NC	11.1, 19.2
		Low value - n (%)	3 (3.8)	0	1 (2.6)	0	4 (2.4)
		Normal value - n (%)	77 (96.3)	41 (100)	37 (94.9)	3 (60.0)	158 (95.8)
		High value - n (%)	0	0	1 (2.6)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	0	2 (5.1)	0	5 (3.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Hemoglobin (g/dL) Day 0		Hemoglobin decreased					
		Grade 0 - n (%)	74 (92.5)	38 (92.7)	34 (87.2)	3 (60.0)	149 (90.3)
		Grade 1 - n (%)	5 (6.3)	3 (7.3)	5 (12.8)	0	13 (7.9)
		Grade 2 - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Hemoglobin increase					
		Grade 0 - n (%)	80 (100)	41 (100)	38 (97.4)	3 (60.0)	162 (98.2)
		Grade 1 - n (%)	0	0	1 (2.6)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Hematocrit (%)	Screening	n	80	41	39	4	164
		Mean (SD)	42.84 (3.743)	44.01 (3.086)	43.34 (3.771)	45.58 (3.337)	43.32 (3.606)
		Median	42.80	44.00	43.40	45.75	43.50
		Min, Max	33.8, 49.6	35.6, 50.7	35.0, 53.2	42.3, 48.5	33.8, 53.2
		Low value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Normal value - n (%)	79 (98.8)	41 (100)	37 (94.9)	4 (80.0)	161 (97.6)
		High value - n (%)	0	0	2 (5.1)	0	2 (1.2)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	2 (5.1)	0	3 (1.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Hematocrit (%)	Day 0	n	79	41	39	3	162
		Mean (SD)	44.37 (3.995)	45.27 (3.634)	44.95 (3.947)	NC	44.78 (3.916)
		Median	45.00	45.00	45.00	NC	45.00
		Min, Max	36.0, 51.0	37.0, 54.0	36.0, 57.0	NC	36.0, 57.0
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	79 (98.8)	40 (97.6)	38 (97.4)	3 (60.0)	160 (97.0)
		High value - n (%)	0	1 (2.4)	1 (2.6)	0	2 (1.2)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	1 (2.6)	0	2 (1.2)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Leukocytes (G/L)	Screening	n	80	41	39	4	164
		Mean (SD)	7.905 (2.0183)	7.388 (1.6800)	7.705 (2.2076)	8.625 (1.8173)	7.746 (1.9818)
		Median	7.750	7.200	7.400	9.200	7.450
		Min, Max	4.20, 13.20	4.60, 10.60	3.30, 13.50	6.10, 10.00	3.30, 13.50
		Low value - n (%)	0	0	1 (2.6)	0	1 (0.6)
		Normal value - n (%)	75 (93.8)	41 (100)	35 (89.7)	4 (80.0)	155 (93.9)
		High value - n (%)	5 (6.3)	0	3 (7.7)	0	8 (4.8)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	5 (6.3)	0	4 (10.3)	0	9 (5.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Leukocytes (GI/L)	Screening	WBC Decrease					
		Grade 0 - n (%)	80 (100)	41 (100)	38 (97.4)	4 (80.0)	163 (98.8)
		Grade 1 - n (%)	0	0	1 (2.6)	0	1 (0.6)
		WBC Increase					
		Grade 0 - n (%)	75 (93.8)	41 (100)	36 (92.3)	4 (80.0)	156 (94.5)
		Grade 1 - n (%)	5 (6.3)	0	3 (7.7)	0	8 (4.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Leukocytes (GI/L)	Day 0	n	80	41	39	3	163
		Mean (SD)	7.760 (1.7661)	8.350 (1.8777)	7.926 (2.3282)	NC	7.938 (1.9324)
		Median	7.535	8.010	7.430	NC	7.600
		Min, Max	3.91, 13.07	5.13, 11.97	3.59, 13.55	NC	3.59, 13.55
		Low value - n (%)	0	0	1 (2.6)	0	1 (0.6)
		Normal value - n (%)	74 (92.5)	35 (85.4)	32 (82.1)	3 (60.0)	144 (87.3)
		High value - n (%)	6 (7.5)	6 (14.6)	6 (15.4)	0	18 (10.9)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	6 (7.5)	6 (14.6)	7 (17.9)	0	19 (11.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Leukocytes (GI/L)	Day 0	WBC Decrease					
		Grade 0 - n (%)	80 (100)	41 (100)	38 (97.4)	3 (60.0)	162 (98.2)
		Grade 1 - n (%)	0	0	1 (2.6)	0	1 (0.6)
		WBC Increase					
		Grade 0 - n (%)	75 (93.8)	35 (85.4)	33 (84.6)	3 (60.0)	146 (88.5)
		Grade 1 - n (%)	5 (6.3)	6 (14.6)	6 (15.4)	0	17 (10.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Neutrophils/leuko cytes (%)	Screening	n	80	41	39	4	164
		Mean (SD)	58.29 (9.184)	57.00 (8.643)	57.13 (9.016)	63.25 (3.775)	57.81 (8.918)
		Median	59.00	57.00	58.00	63.00	58.00
		Min, Max	38.0, 79.0	29.0, 71.0	38.0, 75.0	59.0, 68.0	29.0, 79.0
		Low value - n (%)	4 (5.0)	1 (2.4)	1 (2.6)	0	6 (3.6)
		Normal value - n (%)	72 (90.0)	40 (97.6)	37 (94.9)	4 (80.0)	153 (92.7)
		High value - n (%)	4 (5.0)	0	1 (2.6)	0	5 (3.0)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	8 (10.0)	1 (2.4)	2 (5.1)	0	11 (6.7)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Neutrophils/leuko cytes (%)	Day 0	n	80	41	39	3	163
		Mean (SD)	55.80 (9.019)	55.22 (7.910)	55.62 (8.202)	NC	55.61 (8.440)
		Median	56.20	55.10	55.80	NC	56.10
		Min, Max	31.9, 76.1	39.5, 80.0	38.6, 73.9	NC	31.9, 80.0
		Low value - n (%)	6 (7.5)	1 (2.4)	2 (5.1)	0	9 (5.5)
		Normal value - n (%)	72 (90.0)	39 (95.1)	37 (94.9)	3 (60.0)	151 (91.5)
		High value - n (%)	2 (2.5)	1 (2.4)	0	0	3 (1.8)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	8 (10.0)	2 (4.9)	2 (5.1)	0	12 (7.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Lymphocytes/leukocytes (%)	Screening	n	80	41	39	4	164
		Mean (SD)	31.95 (8.120)	33.15 (7.252)	33.23 (8.045)	28.75 (2.062)	32.48 (7.794)
		Median	32.00	32.00	32.00	29.00	32.00
		Min, Max	14.0, 52.0	21.0, 52.0	20.0, 55.0	26.0, 31.0	14.0, 55.0
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	75 (93.8)	39 (95.1)	36 (92.3)	4 (80.0)	154 (93.3)
		High value - n (%)	5 (6.3)	2 (4.9)	3 (7.7)	0	10 (6.1)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	5 (6.3)	2 (4.9)	3 (7.7)	0	10 (6.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Lymphocytes/leukocytes (%)	Day 0	n	80	41	39	3	163
		Mean (SD)	35.35 (8.589)	35.89 (7.796)	35.61 (7.879)	NC	35.53 (8.116)
		Median	34.60	36.30	35.80	NC	35.80
		Min, Max	17.6, 58.8	13.1, 53.0	19.0, 49.7	NC	13.1, 58.8
		Low value - n (%)	0	1 (2.4)	0	0	1 (0.6)
		Normal value - n (%)	74 (92.5)	39 (95.1)	37 (94.9)	3 (60.0)	153 (92.7)
		High value - n (%)	6 (7.5)	1 (2.4)	2 (5.1)	0	9 (5.5)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	6 (7.5)	2 (4.9)	2 (5.1)	0	10 (6.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Monocytes/leukocytes (%)	Screening	n	80	41	39	4	164
		Mean (SD)	6.99 (1.873)	6.63 (1.445)	7.05 (1.792)	6.00 (0.817)	6.89 (1.738)
		Median	7.00	6.00	7.00	6.00	7.00
		Min, Max	3.0, 13.0	4.0, 9.0	4.0, 11.0	5.0, 7.0	3.0, 13.0
		Low value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Normal value - n (%)	78 (97.5)	41 (100)	39 (100)	4 (80.0)	162 (98.2)
		High value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	0	0	0	2 (1.2)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Monocytes/leukocytes (%)	Day 0	n	80	41	39	3	163
		Mean (SD)	5.48 (1.636)	5.43 (1.605)	5.33 (1.316)	NC	5.45 (1.545)
		Median	5.20	5.20	5.30	NC	5.20
		Min, Max	2.5, 12.3	2.9, 10.0	2.8, 8.8	NC	2.5, 12.3
		Low value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Normal value - n (%)	78 (97.5)	41 (100)	39 (100)	3 (60.0)	161 (97.6)
		High value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	0	0	0	2 (1.2)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Eosinophils/leuko cytes (%)	Screening	n	80	41	39	4	164
		Mean (SD)	2.35 (1.502)	2.73 (2.259)	2.28 (1.686)	1.75 (0.958)	2.41 (1.752)
		Median	2.00	2.00	2.00	1.50	2.00
		Min, Max	1.0, 7.0	0.0, 11.0	0.0, 9.0	1.0, 3.0	0.0, 11.0
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	75 (93.8)	38 (92.7)	38 (97.4)	4 (80.0)	155 (93.9)
		High value - n (%)	5 (6.3)	3 (7.3)	1 (2.6)	0	9 (5.5)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	5 (6.3)	3 (7.3)	1 (2.6)	0	9 (5.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Eosinophils/leuko cytes (%)	Day 0	n	80	41	39	3	163
		Mean (SD)	2.77 (1.219)	2.87 (1.354)	2.79 (1.644)	NC	2.80 (1.351)
		Median	2.60	2.70	2.60	NC	2.60
		Min, Max	0.5, 6.3	1.0, 6.4	0.5, 8.3	NC	0.5, 8.3
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	38 (97.4)	3 (60.0)	162 (98.2)
		High value - n (%)	0	0	1 (2.6)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	0	1 (2.6)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Basophils/leukocytes (%)	Screening	n	80	41	39	4	164
		Mean (SD)	0.39 (0.516)	0.49 (0.554)	0.31 (0.468)	0.25 (0.500)	0.39 (0.514)
		Median	0.00	0.00	0.00	0.00	0.00
		Min, Max	0.0, 2.0	0.0, 2.0	0.0, 1.0	0.0, 1.0	0.0, 2.0
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	4 (80.0)	164 (99.4)
		High value - n (%)	0	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Basophils/leukocytes (%)	Day 0	n	80	41	39	3	163
		Mean (SD)	0.61 (0.295)	0.60 (0.258)	0.64 (0.340)	NC	0.61 (0.294)
		Median	0.60	0.60	0.60	NC	0.60
		Min, Max	0.1, 1.8	0.2, 1.4	0.3, 2.3	NC	0.1, 2.3
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	38 (97.4)	3 (60.0)	162 (98.2)
		High value - n (%)	0	0	1 (2.6)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	0	1 (2.6)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Platelets (GI/L)	Screening	n	80	41	39	4	164
		Mean (SD)	277.9 (55.66)	273.9 (55.34)	274.1 (73.71)	272.3 (86.97)	275.8 (60.52)
		Median	275.5	278.0	267.0	266.0	271.0
		Min, Max	149, 438	179, 441	170, 506	197, 360	149, 506
		Low value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Normal value - n (%)	76 (95.0)	39 (95.1)	35 (89.7)	4 (80.0)	154 (93.3)
		High value - n (%)	3 (3.8)	2 (4.9)	4 (10.3)	0	9 (5.5)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	2 (4.9)	4 (10.3)	0	10 (6.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Platelets (GI/L)	Screening	Platelets Decrease					
		Grade 0 - n (%)	79 (98.8)	41 (100)	39 (100)	4 (80.0)	163 (98.8)
		Grade 1 - n (%)	1 (1.3)	0	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.7

Study ID: ZRHM-REXA-08-US

Program: t_labhema.sas

Status: Final

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Platelets (GI/L)	Day 0	n	80	41	39	3	163
		Mean (SD)	275.1 (64.60)	290.4 (68.57)	287.3 (90.52)	NC	282.7 (72.49)
		Median	257.0	290.0	269.0	NC	275.0
		Min, Max	111, 482	187, 537	141, 563	NC	111, 563
		Low value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Normal value - n (%)	76 (95.0)	39 (95.1)	35 (89.7)	3 (60.0)	153 (92.7)
		High value - n (%)	3 (3.8)	2 (4.9)	4 (10.3)	0	9 (5.5)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	2 (4.9)	4 (10.3)	0	10 (6.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Platelets (GI/L)	Day 0	Platelets Decrease					
		Grade 0 - n (%)	79 (98.8)	41 (100)	39 (100)	3 (60.0)	162 (98.2)
		Grade 1 - n (%)	1 (1.3)	0	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Ery. mean corpuscular hemoglobin (pg)	Screening	n	80	41	39	4	164
		Mean (SD)	30.29 (2.052)	30.51 (2.164)	30.06 (2.717)	29.80 (3.091)	30.28 (2.262)
		Median	30.70	30.60	31.10	31.15	30.70
		Min, Max	24.3, 34.6	23.4, 35.9	22.3, 33.5	25.2, 31.7	22.3, 35.9
		Low value - n (%)	5 (6.3)	2 (4.9)	4 (10.3)	1 (20.0)	12 (7.3)
		Normal value - n (%)	71 (88.8)	36 (87.8)	31 (79.5)	3 (60.0)	141 (85.5)
		High value - n (%)	4 (5.0)	3 (7.3)	4 (10.3)	0	11 (6.7)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	9 (11.3)	5 (12.2)	8 (20.5)	1 (20.0)	23 (13.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Ery. mean corpuscular hemoglobin (pg)	Day 0	n	80	41	39	3	163
		Mean (SD)	30.19 (1.930)	30.39 (2.048)	29.74 (2.468)	NC	30.14 (2.085)
		Median	30.00	31.00	31.00	NC	30.00
		Min, Max	24.0, 34.0	23.0, 35.0	23.0, 33.0	NC	23.0, 35.0
		Low value - n (%)	2 (2.5)	1 (2.4)	4 (10.3)	0	7 (4.2)
		Normal value - n (%)	78 (97.5)	39 (95.1)	35 (89.7)	3 (60.0)	155 (93.9)
		High value - n (%)	0	1 (2.4)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	2 (4.9)	4 (10.3)	0	8 (4.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Ery. mean corpuscular hgb concentration (g/dL)	Screening	n	80	41	39	4	164
		Mean (SD)	33.51 (1.042)	33.57 (0.877)	33.59 (1.066)	34.25 (0.777)	33.57 (1.002)
		Median	33.60	33.70	33.80	34.55	33.70
		Min, Max	31.1, 35.9	31.5, 35.6	30.9, 35.0	33.1, 34.8	30.9, 35.9
		Low value - n (%)	3 (3.8)	0	2 (5.1)	0	5 (3.0)
		Normal value - n (%)	76 (95.0)	41 (100)	37 (94.9)	4 (80.0)	158 (95.8)
		High value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	0	2 (5.1)	0	6 (3.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Ery. mean corpuscular hgb concentration (g/dL)	Day 0	n	79	41	39	3	162
		Mean (SD)	33.05 (1.143)	33.10 (1.068)	33.05 (1.235)	NC	33.08 (1.142)
		Median	33.00	33.00	33.00	NC	33.00
		Min, Max	30.0, 35.0	30.0, 35.0	30.0, 36.0	NC	30.0, 36.0
		Low value - n (%)	1 (1.3)	1 (2.4)	2 (5.1)	0	4 (2.4)
		Normal value - n (%)	78 (97.5)	40 (97.6)	37 (94.9)	3 (60.0)	158 (95.8)
		High value - n (%)	0	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	1 (2.4)	2 (5.1)	0	4 (2.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Ery. mean corpuscular volume (fL)	Screening	n	80	41	39	4	164
		Mean (SD)	90.4 (4.71)	90.9 (5.37)	89.4 (6.35)	86.8 (7.23)	90.2 (5.36)
		Median	91.0	90.0	91.0	90.0	91.0
		Min, Max	78, 101	74, 106	72, 99	76, 91	72, 106
		Low value - n (%)	2 (2.5)	1 (2.4)	4 (10.3)	1 (20.0)	8 (4.8)
		Normal value - n (%)	74 (92.5)	38 (92.7)	33 (84.6)	3 (60.0)	148 (89.7)
		High value - n (%)	4 (5.0)	2 (4.9)	2 (5.1)	0	8 (4.8)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	6 (7.5)	3 (7.3)	6 (15.4)	1 (20.0)	16 (9.7)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Ery. mean corpuscular volume (fL)	Day 0	n	79	41	39	3	162
		Mean (SD)	91.3 (4.97)	91.6 (4.86)	89.9 (6.07)	NC	91.0 (5.19)
		Median	92.0	92.0	92.0	NC	92.0
		Min, Max	77, 102	77, 103	74, 98	NC	74, 103
		Low value - n (%)	1 (1.3)	1 (2.4)	2 (5.1)	0	4 (2.4)
		Normal value - n (%)	72 (90.0)	36 (87.8)	36 (92.3)	3 (60.0)	147 (89.1)
		High value - n (%)	6 (7.5)	4 (9.8)	1 (2.6)	0	11 (6.7)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	7 (8.8)	5 (12.2)	3 (7.7)	0	15 (9.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (T/L)	Baseline	n	80	41	39	160
		Mean (SD)	4.871 (0.4238)	4.959 (0.4296)	5.010 (0.4279)	4.928 (0.4277)
		Median	4.850	4.900	5.000	4.900
		Min, Max	3.80, 5.90	3.80, 5.90	4.20, 6.30	3.80, 6.30
		Low value - n (%)	4 (5.0)	1 (2.4)	1 (2.6)	6 (3.8)
		Normal value - n (%)	76 (95.0)	39 (95.1)	38 (97.4)	153 (95.6)
		High value - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	2 (4.9)	1 (2.6)	7 (4.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (T/L)	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	4.733 (0.4216)	4.793 (0.4185)	4.909 (0.3745)	4.788 (0.4140)
		Median	4.750	4.700	4.900	4.800
		Min, Max	3.70, 5.80	3.80, 5.50	4.20, 5.70	3.70, 5.80
		Low value - n (%)	9 (11.3)	3 (7.3)	0	12 (7.5)
		Normal value - n (%)	71 (88.8)	37 (90.2)	35 (89.7)	143 (89.4)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	8 (10.0)	3 (7.3)	0	11 (6.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (T/L)	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	-0.139 (0.1952)	-0.175 (0.2216)	-0.114 (0.2172)	-0.143 (0.2071)
		Median	-0.100	-0.200	-0.100	-0.100
		Min, Max	-0.60, 0.40	-0.50, 0.40	-0.60, 0.40	-0.60, 0.40

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (T/L)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Low, NCS to Low, NCS - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		Low, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n (%)	5 (6.3)	2 (4.9)	0	7 (4.4)
		Normal to Normal - n (%)	70 (87.5)	36 (87.8)	35 (89.7)	141 (88.1)
		High, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (T/L)	Day 30	n	76	38	33	147
		Mean (SD)	4.695 (0.4160)	4.821 (0.3954)	4.815 (0.3907)	4.754 (0.4072)
		Median	4.700	4.850	4.800	4.800
		Min, Max	3.70, 5.70	3.70, 5.60	4.00, 5.70	3.70, 5.70
		Low value - n (%)	10 (12.5)	2 (4.9)	3 (7.7)	15 (9.4)
		Normal value - n (%)	66 (82.5)	36 (87.8)	30 (76.9)	132 (82.5)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	10 (12.5)	2 (4.9)	3 (7.7)	15 (9.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (T/L)	Change from Baseline to Day 30	n	76	38	33	147
		Mean (SD)	-0.197 (0.2123)	-0.153 (0.2545)	-0.194 (0.2150)	-0.185 (0.2238)
		Median	-0.200	-0.100	-0.200	-0.200
		Min, Max	-0.80, 0.30	-1.00, 0.30	-0.70, 0.20	-1.00, 0.30

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.7

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (T/L)	Shift in Normality from Baseline to Day 30	Low, NCS to Low, NCS - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		Low, NCS to Normal - n (%)	2 (2.5)	0	0	2 (1.3)
		Normal to Low, NCS - n (%)	8 (10.0)	1 (2.4)	3 (7.7)	12 (7.5)
		Normal to Normal - n (%)	64 (80.0)	35 (85.4)	30 (76.9)	129 (80.6)
		High, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (T/L)	Day 60	n	74	37	31	142
		Mean (SD)	4.789 (0.4183)	4.868 (0.3779)	4.890 (0.3167)	4.832 (0.3879)
		Median	4.750	4.900	4.900	4.800
		Min, Max	3.80, 5.70	3.90, 5.60	4.30, 5.50	3.80, 5.70
		Low value - n (%)	6 (7.5)	1 (2.4)	0	7 (4.4)
		Normal value - n (%)	68 (85.0)	36 (87.8)	31 (79.5)	135 (84.4)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	6 (7.5)	1 (2.4)	0	7 (4.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (T/L)	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	-0.080 (0.2483)	-0.076 (0.2374)	-0.094 (0.2081)	-0.082 (0.2357)
		Median	-0.100	-0.100	-0.100	-0.100
		Min, Max	-0.80, 0.60	-0.60, 0.40	-0.50, 0.20	-0.80, 0.60

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.7

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (T/L)	Shift in Normality from Baseline to Day 60	Low, NCS to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Low, NCS to Normal - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		Normal to Low, NCS - n (%)	5 (6.3)	1 (2.4)	0	6 (3.8)
		Normal to Normal - n (%)	65 (81.3)	34 (82.9)	31 (79.5)	130 (81.3)
		High, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (T/L)	Day 91/Discharge n Ambulatory		73	36	33	142
		Mean (SD)	4.852 (0.4662)	4.961 (0.3760)	4.967 (0.3943)	4.906 (0.4295)
		Median	4.800	4.950	5.000	4.900
		Min, Max	3.90, 6.10	3.80, 5.60	4.30, 5.70	3.80, 6.10
		Low value - n (%)	3 (3.8)	1 (2.4)	1 (2.6)	5 (3.1)
		Normal value - n (%)	70 (87.5)	35 (85.4)	32 (82.1)	137 (85.6)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	1 (2.4)	1 (2.6)	5 (3.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.7

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (T/L)	Change from Baseline to Day 91/Discharge Ambulatory	n	73	36	33	142
		Mean (SD)	-0.014 (0.2552)	0.011 (0.2562)	-0.042 (0.2862)	-0.014 (0.2617)
		Median	0.000	0.000	-0.100	0.000
		Min, Max	-0.80, 0.90	-0.50, 0.40	-0.60, 0.50	-0.80, 0.90

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (T/L)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Low, NCS to Low, NCS - n (%)	0	1 (2.4)	0	1 (0.6)
		Low, NCS to Normal - n (%)	4 (5.0)	0	0	4 (2.5)
		Normal to Low, NCS - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		Normal to Normal - n (%)	66 (82.5)	34 (82.9)	32 (82.1)	132 (82.5)
		High, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Baseline	n	80	41	39	160
		Mean (SD)	14.63 (1.445)	14.97 (1.217)	14.87 (1.487)	14.77 (1.400)
		Median	14.90	15.10	15.10	15.00
		Min, Max	11.2, 17.7	11.9, 17.5	11.1, 19.2	11.1, 19.2
		Low value - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		Normal value - n (%)	77 (96.3)	41 (100)	37 (94.9)	155 (96.9)
		High value - n (%)	0	0	1 (2.6)	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	0	2 (5.1)	5 (3.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Baseline	Hemoglobin decreased				
		Grade 0 - n (%)	74 (92.5)	38 (92.7)	34 (87.2)	146 (91.3)
		Grade 1 - n (%)	5 (6.3)	3 (7.3)	5 (12.8)	13 (8.1)
		Grade 2 - n (%)	1 (1.3)	0	0	1 (0.6)
		Hemoglobin increase				
		Grade 0 - n (%)	80 (100)	41 (100)	38 (97.4)	159 (99.4)
		Grade 1 - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	14.25 (1.429)	14.52 (1.244)	14.41 (1.448)	14.36 (1.384)
		Median	14.55	14.50	14.60	14.50
		Min, Max	10.6, 16.6	11.0, 16.7	10.2, 17.7	10.2, 17.7
		Low value - n (%)	6 (7.5)	1 (2.4)	2 (5.1)	9 (5.6)
		Normal value - n (%)	74 (92.5)	39 (95.1)	33 (84.6)	146 (91.3)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	5 (6.3)	1 (2.4)	2 (5.1)	8 (5.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Day 6/Discharge Confinement	Hemoglobin decreased				
		Grade 0 - n (%)	22 (27.5)	10 (24.4)	9 (23.1)	41 (25.6)
		Grade 1 - n (%)	53 (66.3)	30 (73.2)	24 (61.5)	107 (66.9)
		Grade 2 - n (%)	5 (6.3)	0	2 (5.1)	7 (4.4)
		Hemoglobin increase				
		Grade 0 - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	-0.38 (0.592)	-0.45 (0.614)	-0.41 (0.589)	-0.40 (0.593)
		Median	-0.40	-0.60	-0.40	-0.50
		Min, Max	-1.6, 1.4	-1.3, 1.3	-1.9, 0.8	-1.9, 1.4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Low, NCS to Low, NCS - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		Normal to Low - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n (%)	2 (2.5)	1 (2.4)	1 (2.6)	4 (2.5)
		Normal to Normal - n (%)	74 (92.5)	39 (95.1)	33 (84.6)	146 (91.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	Hemoglobin decreased				
		0 to 0 - n (%)	21 (26.3)	9 (22.0)	9 (23.1)	39 (24.4)
		0 to 1 - n (%)	52 (65.0)	28 (68.3)	20 (51.3)	100 (62.5)
		0 to 2 - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		1 to 0 - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		1 to 1 - n (%)	1 (1.3)	2 (4.9)	4 (10.3)	7 (4.4)
		1 to 2 - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		2 to 2 - n (%)	1 (1.3)	0	0	1 (0.6)
		Hemoglobin increase				
		0 to 0 - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Day 30	n	76	38	33	147
		Mean (SD)	14.08 (1.496)	14.56 (1.345)	14.16 (1.605)	14.22 (1.488)
		Median	14.30	14.65	14.40	14.50
		Min, Max	10.4, 17.1	10.9, 17.1	10.0, 17.9	10.0, 17.9
		Low value - n (%)	7 (8.8)	3 (7.3)	4 (10.3)	14 (8.8)
		Normal value - n (%)	69 (86.3)	35 (85.4)	29 (74.4)	133 (83.1)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal NCS - n (%)	7 (8.8)	2 (4.9)	4 (10.3)	13 (8.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Day 30	Hemoglobin decreased				
		Grade 0 - n (%)	14 (17.5)	12 (29.3)	6 (15.4)	32 (20.0)
		Grade 1 - n (%)	53 (66.3)	23 (56.1)	23 (59.0)	99 (61.9)
		Grade 2 - n (%)	8 (10.0)	1 (2.4)	3 (7.7)	12 (7.5)
		Grade 3 - n (%)	1 (1.3)	2 (4.9)	1 (2.6)	4 (2.5)
		Hemoglobin increase				
		Grade 0 - n (%)	76 (95.0)	38 (92.7)	33 (84.6)	147 (91.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Change from Baseline to Day 30	n	76	38	33	147
		Mean (SD)	-0.61 (0.644)	-0.43 (0.723)	-0.59 (0.637)	-0.56 (0.664)
		Median	-0.60	-0.40	-0.60	-0.50
		Min, Max	-2.4, 0.9	-2.4, 0.7	-2.3, 0.4	-2.4, 0.9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Shift in Normality from Baseline to Day 30	Low, NCS to Low, NCS - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		Normal to Low, NCS - n (%)	4 (5.0)	2 (4.9)	3 (7.7)	9 (5.6)
		Normal to Low, CS - n (%)	0	1 (2.4)	0	1 (0.6)
		Normal to Normal - n (%)	69 (86.3)	35 (85.4)	29 (74.4)	133 (83.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Shift in Toxicity from Baseline to Day 30	Hemoglobin decreased				
		0 to 0 - n (%)	14 (17.5)	10 (24.4)	6 (15.4)	30 (18.8)
		0 to 1 - n (%)	52 (65.0)	22 (53.7)	20 (51.3)	94 (58.8)
		0 to 2 - n (%)	4 (5.0)	1 (2.4)	1 (2.6)	6 (3.8)
		0 to 3 - n (%)	1 (1.3)	2 (4.9)	1 (2.6)	4 (2.5)
		1 to 0 - n (%)	0	2 (4.9)	0	2 (1.3)
		1 to 1 - n (%)	1 (1.3)	1 (2.4)	3 (7.7)	5 (3.1)
		1 to 2 - n (%)	3 (3.8)	0	2 (5.1)	5 (3.1)
		2 to 2 - n (%)	1 (1.3)	0	0	1 (0.6)
		Hemoglobin increase				
		0 to 0 - n (%)	76 (95.0)	38 (92.7)	33 (84.6)	147 (91.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Day 60	n	74	37	31	142
		Mean (SD)	14.19 (1.519)	14.73 (1.342)	14.35 (1.473)	14.37 (1.472)
		Median	14.50	15.10	14.70	14.70
		Min, Max	10.7, 17.1	10.8, 16.6	9.4, 16.6	9.4, 17.1
		Low value - n (%)	8 (10.0)	2 (4.9)	3 (7.7)	13 (8.1)
		Normal value - n (%)	66 (82.5)	35 (85.4)	28 (71.8)	129 (80.6)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	8 (10.0)	2 (4.9)	3 (7.7)	13 (8.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Day 60	Hemoglobin decreased				
		Grade 0 - n (%)	23 (28.8)	15 (36.6)	10 (25.6)	48 (30.0)
		Grade 1 - n (%)	43 (53.8)	20 (48.8)	18 (46.2)	81 (50.6)
		Grade 2 - n (%)	5 (6.3)	2 (4.9)	2 (5.1)	9 (5.6)
		Grade 3 - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		Hemoglobin increase				
		Grade 0 - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	-0.42 (0.771)	-0.20 (0.768)	-0.46 (0.642)	-0.37 (0.746)
		Median	-0.40	-0.20	-0.50	-0.35
		Min, Max	-2.6, 1.3	-2.0, 1.1	-1.7, 0.6	-2.6, 1.3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.7

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Shift in Normality from Baseline to Day 60	Low, NCS to Low, NCS - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		Normal to Low, NCS - n (%)	5 (6.3)	2 (4.9)	2 (5.1)	9 (5.6)
		Normal to Normal - n (%)	66 (82.5)	35 (85.4)	28 (71.8)	129 (80.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.7

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Shift in Toxicity from Baseline to Day 60	Hemoglobin decreased				
		0 to 0 - n (%)	22 (27.5)	14 (34.1)	9 (23.1)	45 (28.1)
		0 to 1 - n (%)	42 (52.5)	18 (43.9)	17 (43.6)	77 (48.1)
		0 to 2 - n (%)	1 (1.3)	2 (4.9)	1 (2.6)	4 (2.5)
		0 to 3 - n (%)	3 (3.8)	0	0	3 (1.9)
		1 to 0 - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		1 to 1 - n (%)	1 (1.3)	2 (4.9)	1 (2.6)	4 (2.5)
		1 to 2 - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		1 to 3 - n (%)	0	0	1 (2.6)	1 (0.6)
		2 to 2 - n (%)	1 (1.3)	0	0	1 (0.6)
Hemoglobin (g/dL)		Hemoglobin increase				
		0 to 0 - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Day 91/Discharge n Ambulatory		73	36	33	142
		Mean (SD)	14.27 (1.558)	14.86 (1.284)	14.49 (1.543)	14.47 (1.499)
		Median	14.20	15.00	14.60	14.70
		Min, Max	10.6, 16.7	11.8, 16.9	9.8, 16.8	9.8, 16.9
		Low value - n (%)	4 (5.0)	0	2 (5.1)	6 (3.8)
		Normal value - n (%)	69 (86.3)	36 (87.8)	31 (79.5)	136 (85.0)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	0	2 (5.1)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Day 91/Discharge Ambulatory	Hemoglobin decreased				
		Grade 0 - n (%)	22 (27.5)	18 (43.9)	11 (28.2)	51 (31.9)
		Grade 1 - n (%)	45 (56.3)	18 (43.9)	21 (53.8)	84 (52.5)
		Grade 2 - n (%)	4 (5.0)	0	1 (2.6)	5 (3.1)
		Grade 3 - n (%)	2 (2.5)	0	0	2 (1.3)
		Hemoglobin increase				
		Grade 0 - n (%)	73 (91.3)	36 (87.8)	33 (84.6)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Change from Baseline to Day 91/Discharge Ambulatory	n	73	36	33	142
		Mean (SD)	-0.31 (0.697)	-0.12 (0.781)	-0.26 (0.760)	-0.25 (0.733)
		Median	-0.30	0.00	-0.40	-0.30
		Min, Max	-2.3, 1.4	-1.4, 1.2	-1.5, 1.5	-2.3, 1.5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Low, NCS to Low, NCS - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		Normal to Low, NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		Normal to Normal - n (%)	69 (86.3)	36 (87.8)	31 (79.5)	136 (85.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hemoglobin (g/dL)	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	Hemoglobin decreased				
		0 to 0 - n (%)	21 (26.3)	16 (39.0)	10 (25.6)	47 (29.4)
		0 to 1 - n (%)	42 (52.5)	17 (41.5)	18 (46.2)	77 (48.1)
		0 to 2 - n (%)	2 (2.5)	0	0	2 (1.3)
		0 to 3 - n (%)	2 (2.5)	0	0	2 (1.3)
		1 to 0 - n (%)	1 (1.3)	2 (4.9)	1 (2.6)	4 (2.5)
		1 to 1 - n (%)	3 (3.8)	1 (2.4)	3 (7.7)	7 (4.4)
		1 to 2 - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		2 to 2 - n (%)	1 (1.3)	0	0	1 (0.6)
		Hemoglobin increase				
		0 to 0 - n (%)	73 (91.3)	36 (87.8)	33 (84.6)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hematocrit (%)	Baseline	n	79	41	39	159
		Mean (SD)	44.37 (3.995)	45.27 (3.634)	44.95 (3.947)	44.74 (3.889)
		Median	45.00	45.00	45.00	45.00
		Min, Max	36.0, 51.0	37.0, 54.0	36.0, 57.0	36.0, 57.0
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	79 (98.8)	40 (97.6)	38 (97.4)	157 (98.1)
		High value - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hematocrit (%)	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	42.84 (3.850)	43.48 (3.412)	43.54 (3.665)	43.16 (3.692)
		Median	43.00	43.00	44.00	43.00
		Min, Max	33.0, 51.0	34.0, 51.0	34.0, 51.0	33.0, 51.0
		Low value - n (%)	3 (3.8)	0	0	3 (1.9)
		Normal value - n (%)	77 (96.3)	39 (95.1)	34 (87.2)	150 (93.8)
		High value - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	1 (2.4)	1 (2.6)	5 (3.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hematocrit (%)	Change from Baseline to Day 6/Discharge Confinement	n	79	40	35	154
		Mean (SD)	-1.51 (1.860)	-1.80 (2.127)	-1.31 (2.084)	-1.54 (1.978)
		Median	-2.00	-2.00	-1.00	-2.00
		Min, Max	-7.0, 5.0	-5.0, 4.0	-6.0, 3.0	-7.0, 5.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hematocrit (%)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Low, NCS - n (%)	3 (3.8)	0	0	3 (1.9)
		Normal to Normal - n (%)	76 (95.0)	39 (95.1)	34 (87.2)	149 (93.1)
		Normal to High, NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		High, NCS to High, NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hematocrit (%)	Day 30	n	75	36	32	143
		Mean (SD)	43.13 (3.954)	44.75 (3.367)	43.09 (4.269)	43.53 (3.927)
		Median	44.00	45.00	43.00	44.00
		Min, Max	33.0, 50.0	34.0, 50.0	32.0, 53.0	32.0, 53.0
		Low value - n (%)	1 (1.3)	0	2 (5.1)	3 (1.9)
		Normal value - n (%)	74 (92.5)	36 (87.8)	30 (76.9)	140 (87.5)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	2 (5.1)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hematocrit (%)	Change from Baseline to Day 30	n	74	36	32	142
		Mean (SD)	-1.34 (2.103)	-0.92 (2.623)	-1.53 (2.244)	-1.27 (2.270)
		Median	-2.00	-1.00	-2.00	-1.00
		Min, Max	-6.0, 4.0	-8.0, 5.0	-8.0, 2.0	-8.0, 5.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hematocrit (%)	Shift in Normality from Baseline to Day 30	Normal to Low, NCS - n (%)	1 (1.3)	0	2 (5.1)	3 (1.9)
		Normal to Normal - n (%)	73 (91.3)	35 (85.4)	30 (76.9)	138 (86.3)
		High, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hematocrit (%)	Day 60	n	74	37	31	142
		Mean (SD)	44.24 (4.230)	45.24 (3.563)	44.52 (3.714)	44.56 (3.951)
		Median	44.00	46.00	45.00	45.00
		Min, Max	34.0, 53.0	35.0, 53.0	33.0, 50.0	33.0, 53.0
		Low value - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal value - n (%)	72 (90.0)	37 (90.2)	30 (76.9)	139 (86.9)
		High value - n (%)	2 (2.5)	0	0	2 (1.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hematocrit (%)	Change from Baseline to Day 60	n	73	37	31	141
		Mean (SD)	-0.07 (2.563)	0.00 (2.439)	-0.23 (2.262)	-0.09 (2.451)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-6.0, 6.0	-4.0, 6.0	-5.0, 5.0	-6.0, 6.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hematocrit (%)	Shift in Normality from Baseline to Day 60	Normal to Low, NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal to Normal - n (%)	71 (88.8)	36 (87.8)	30 (76.9)	137 (85.6)
		Normal to High, NCS - n (%)	2 (2.5)	0	0	2 (1.3)
		High, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hematocrit (%)	Day 91/Discharge n Ambulatory		73	35	33	141
		Mean (SD)	44.53 (4.479)	45.89 (4.086)	44.73 (3.778)	44.91 (4.237)
		Median	45.00	46.00	45.00	45.00
		Min, Max	35.0, 53.0	36.0, 52.0	34.0, 51.0	34.0, 53.0
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	73 (91.3)	34 (82.9)	33 (84.6)	140 (87.5)
		High value - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hematocrit (%)	Change from Baseline to Day 91/Discharge Ambulatory	n	72	35	33	140
		Mean (SD)	0.32 (2.711)	0.69 (3.066)	0.03 (2.823)	0.34 (2.818)
		Median	0.00	0.00	-1.00	0.00
		Min, Max	-8.0, 7.0	-5.0, 6.0	-6.0, 7.0	-8.0, 7.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Hematocrit (%)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Normal - n (%)	72 (90.0)	33 (80.5)	33 (84.6)	138 (86.3)
		Normal to High, NCS - n (%)	0	1 (2.4)	0	1 (0.6)
		High, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Baseline	n	80	41	39	160
		Mean (SD)	7.760 (1.7661)	8.350 (1.8777)	7.926 (2.3282)	7.952 (1.9472)
		Median	7.535	8.010	7.430	7.665
		Min, Max	3.91, 13.07	5.13, 11.97	3.59, 13.55	3.59, 13.55
		Low value - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal value - n (%)	74 (92.5)	35 (85.4)	32 (82.1)	141 (88.1)
		High value - n (%)	6 (7.5)	6 (14.6)	6 (15.4)	18 (11.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	6 (7.5)	6 (14.6)	7 (17.9)	19 (11.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Baseline	WBC Decrease				
		Grade 0 - n (%)	80 (100)	41 (100)	38 (97.4)	159 (99.4)
		Grade 1 - n (%)	0	0	1 (2.6)	1 (0.6)
		WBC Increase				
		Grade 0 - n (%)	75 (93.8)	35 (85.4)	33 (84.6)	143 (89.4)
		Grade 1 - n (%)	5 (6.3)	6 (14.6)	6 (15.4)	17 (10.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	7.409 (1.8106)	8.246 (1.7864)	7.074 (1.6891)	7.549 (1.8186)
		Median	7.385	8.350	7.050	7.620
		Min, Max	3.91, 11.90	5.16, 11.54	3.31, 11.16	3.31, 11.90
		Low value - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal value - n (%)	76 (95.0)	35 (85.4)	33 (84.6)	144 (90.0)
		High value - n (%)	4 (5.0)	5 (12.2)	1 (2.6)	10 (6.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	5 (12.2)	2 (5.1)	11 (6.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Day 6/Discharge Confinement	WBC Decrease				
		Grade 0 - n (%)	80 (100)	40 (97.6)	34 (87.2)	154 (96.3)
		Grade 1 - n (%)	0	0	1 (2.6)	1 (0.6)
		WBC Increase				
		Grade 0 - n (%)	76 (95.0)	36 (87.8)	34 (87.2)	146 (91.3)
		Grade 1 - n (%)	4 (5.0)	4 (9.8)	1 (2.6)	9 (5.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	-0.351 (1.2870)	-0.059 (1.1850)	-0.822 (1.2997)	-0.382 (1.2845)
		Median	-0.500	0.120	-0.620	-0.430
		Min, Max	-3.66, 3.05	-3.90, 2.09	-4.88, 1.24	-4.88, 3.05

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Shift in Normality from Baseline to Day 6/Discharge Confinement	Low, NCS to Low, NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal to Normal - n (%)	73 (91.3)	33 (80.5)	29 (74.4)	135 (84.4)
		Normal to High, NCS - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		High, NCS to Normal - n (%)	3 (3.8)	2 (4.9)	4 (10.3)	9 (5.6)
		High, NCS to High, NCS - n (%)	3 (3.8)	4 (9.8)	1 (2.6)	8 (5.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	WBC Decrease				
		0 to 0 - n (%)	80 (100)	40 (97.6)	34 (87.2)	154 (96.3)
		1 to 1 - n (%)	0	0	1 (2.6)	1 (0.6)
		WBC Increase				
		0 to 0 - n (%)	74 (92.5)	33 (80.5)	30 (76.9)	137 (85.6)
		0 to 1 - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		1 to 0 - n (%)	2 (2.5)	3 (7.3)	4 (10.3)	9 (5.6)
		1 to 1 - n (%)	3 (3.8)	3 (7.3)	1 (2.6)	7 (4.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Day 30	n	76	38	33	147
		Mean (SD)	7.048 (1.7172)	7.765 (1.8449)	6.981 (2.0708)	7.218 (1.8501)
		Median	6.640	7.525	6.700	6.830
		Min, Max	3.45, 11.35	4.73, 12.45	3.50, 11.62	3.45, 12.45
		Low value - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		Normal value - n (%)	71 (88.8)	36 (87.8)	28 (71.8)	135 (84.4)
		High value - n (%)	4 (5.0)	2 (4.9)	4 (10.3)	10 (6.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	5 (6.3)	2 (4.9)	5 (12.8)	12 (7.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Day 30	WBC Decrease				
		Grade 0 - n (%)	75 (93.8)	38 (92.7)	32 (82.1)	145 (90.6)
		Grade 1 - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		WBC Increase				
		Grade 0 - n (%)	73 (91.3)	36 (87.8)	29 (74.4)	138 (86.3)
		Grade 1 - n (%)	3 (3.8)	2 (4.9)	4 (10.3)	9 (5.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Change from Baseline to Day 30	n	76	38	33	147
		Mean (SD)	-0.770 (1.2980)	-0.603 (1.4473)	-0.879 (1.6767)	-0.751 (1.4220)
		Median	-0.715	-0.395	-0.900	-0.650
		Min, Max	-4.59, 2.99	-4.19, 2.54	-5.49, 2.85	-5.49, 2.99

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Shift in Normality from Baseline to Day 30	Low, NCS to Low, NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	67 (83.8)	32 (78.0)	25 (64.1)	124 (77.5)
		Normal to High, NCS - n (%)	2 (2.5)	0	2 (5.1)	4 (2.5)
		High, NCS to Normal - n (%)	4 (5.0)	4 (9.8)	3 (7.7)	11 (6.9)
		High, NCS to High, NCS - n (%)	2 (2.5)	2 (4.9)	2 (5.1)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Shift in Toxicity from Baseline to Day 30	WBC Decrease				
		0 to 0 - n (%)	75 (93.8)	38 (92.7)	32 (82.1)	145 (90.6)
		0 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)
		1 to 1 - n (%)	0	0	1 (2.6)	1 (0.6)
		WBC Increase				
		0 to 0 - n (%)	70 (87.5)	32 (78.0)	26 (66.7)	128 (80.0)
		0 to 1 - n (%)	1 (1.3)	0	2 (5.1)	3 (1.9)
		1 to 0 - n (%)	3 (3.8)	4 (9.8)	3 (7.7)	10 (6.3)
		1 to 1 - n (%)	2 (2.5)	2 (4.9)	2 (5.1)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Day 60	n	74	37	31	142
		Mean (SD)	7.005 (1.8666)	7.502 (1.5691)	6.798 (1.8284)	7.089 (1.7919)
		Median	6.870	7.760	6.620	7.000
		Min, Max	4.01, 11.71	4.82, 10.45	3.21, 11.20	3.21, 11.71
		Low value - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal value - n (%)	70 (87.5)	37 (90.2)	28 (71.8)	135 (84.4)
		High value - n (%)	4 (5.0)	0	2 (5.1)	6 (3.8)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	0	3 (7.7)	7 (4.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Day 60	WBC Decrease				
		Grade 0 - n (%)	74 (92.5)	37 (90.2)	30 (76.9)	141 (88.1)
		Grade 1 - n (%)	0	0	1 (2.6)	1 (0.6)
		WBC Increase				
		Grade 0 - n (%)	70 (87.5)	37 (90.2)	30 (76.9)	137 (85.6)
		Grade 1 - n (%)	4 (5.0)	0	1 (2.6)	5 (3.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	-0.867 (1.3871)	-0.839 (1.3511)	-1.144 (1.4111)	-0.920 (1.3784)
		Median	-0.820	-0.760	-0.750	-0.775
		Min, Max	-3.88, 2.94	-3.80, 1.26	-4.70, 0.97	-4.70, 2.94

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Shift in Normality from Baseline to Day 60	Low, NCS to Low, NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal to Normal - n (%)	67 (83.8)	32 (78.0)	25 (64.1)	124 (77.5)
		Normal to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to Normal - n (%)	3 (3.8)	5 (12.2)	3 (7.7)	11 (6.9)
		High, NCS to High, NCS - n (%)	3 (3.8)	0	2 (5.1)	5 (3.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Shift in Toxicity from Baseline to Day 60	WBC Decrease				
		0 to 0 - n (%)	74 (92.5)	37 (90.2)	30 (76.9)	141 (88.1)
		1 to 1 - n (%)	0	0	1 (2.6)	1 (0.6)
		WBC Increase				
		0 to 0 - n (%)	67 (83.8)	32 (78.0)	26 (66.7)	125 (78.1)
		0 to 1 - n (%)	2 (2.5)	0	0	2 (1.3)
		1 to 0 - n (%)	3 (3.8)	5 (12.2)	4 (10.3)	12 (7.5)
		1 to 1 - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Day 91/Discharge n Ambulatory		73	36	33	142
		Mean (SD)	6.909 (1.6252)	7.335 (2.1041)	7.146 (2.5515)	7.072 (1.9895)
		Median	6.550	6.735	6.760	6.565
		Min, Max	3.60, 10.69	4.47, 12.98	3.24, 16.72	3.24, 16.72
		Low value - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		Normal value - n (%)	72 (90.0)	34 (82.9)	31 (79.5)	137 (85.6)
		High value - n (%)	0	2 (4.9)	1 (2.6)	3 (1.9)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	2 (4.9)	2 (5.1)	5 (3.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Day 91/Discharge Ambulatory	WBC Decrease				
		Grade 0 - n (%)	72 (90.0)	36 (87.8)	32 (82.1)	140 (87.5)
		Grade 1 - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		WBC Increase				
		Grade 0 - n (%)	73 (91.3)	34 (82.9)	32 (82.1)	139 (86.9)
		Grade 1 - n (%)	0	2 (4.9)	0	2 (1.3)
		Grade 2 - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Change from Baseline to Day 91/Discharge Ambulatory	n	73	36	33	142
		Mean (SD)	-0.928 (1.5635)	-0.916 (1.6688)	-0.714 (1.6931)	-0.875 (1.6118)
		Median	-0.790	-1.215	-0.980	-0.990
		Min, Max	-4.44, 3.56	-4.28, 3.26	-3.82, 5.03	-4.44, 5.03

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Low, NCS to Low, NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	66 (82.5)	31 (75.6)	27 (69.2)	124 (77.5)
		Normal to High, NCS - n (%)	0	1 (2.4)	0	1 (0.6)
		High, NCS to Normal - n (%)	6 (7.5)	3 (7.3)	4 (10.3)	13 (8.1)
		High, NCS to High, NCS - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Leukocytes (G/L) [3.8-10.7]	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	WBC Decrease				
		0 to 0 - n (%)	72 (90.0)	36 (87.8)	32 (82.1)	140 (87.5)
		0 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)
		1 to 1 - n (%)	0	0	1 (2.6)	1 (0.6)
		WBC Increase				
		0 to 0 - n (%)	68 (85.0)	31 (75.6)	28 (71.8)	127 (79.4)
		0 to 1 - n (%)	0	1 (2.4)	0	1 (0.6)
		1 to 0 - n (%)	5 (6.3)	3 (7.3)	4 (10.3)	12 (7.5)
		1 to 1 - n (%)	0	1 (2.4)	0	1 (0.6)
		1 to 2 - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Neutrophils/Leukocytes (%) [40.5-75]	Baseline	n	80	41	39	160
		Mean (SD)	55.80 (9.019)	55.22 (7.910)	55.62 (8.202)	55.61 (8.502)
		Median	56.20	55.10	55.80	56.10
		Min, Max	31.9, 76.1	39.5, 80.0	38.6, 73.9	31.9, 80.0
		Low value - n (%)	6 (7.5)	1 (2.4)	2 (5.1)	9 (5.6)
		Normal value - n (%)	72 (90.0)	39 (95.1)	37 (94.9)	148 (92.5)
		High value - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	8 (10.0)	2 (4.9)	2 (5.1)	12 (7.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Neutrophils/Leukocytes (%) [40.5-75]	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	54.91 (9.260)	54.91 (7.507)	53.28 (9.648)	54.54 (8.904)
		Median	55.90	55.30	56.40	55.50
		Min, Max	28.5, 75.0	38.7, 71.2	28.1, 69.7	28.1, 75.0
		Low value - n (%)	6 (7.5)	3 (7.3)	4 (10.3)	13 (8.1)
		Normal value - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	6 (7.5)	3 (7.3)	4 (10.3)	13 (8.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Neutrophils/Leukocytes (%) [40.5-75]	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	-0.89 (5.719)	-0.22 (5.816)	-2.13 (6.064)	-1.00 (5.824)
		Median	-1.25	0.00	-2.30	-1.20
		Min, Max	-14.3, 25.6	-20.7, 9.3	-16.6, 16.9	-20.7, 25.6

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Neutrophils/Leukocytes (%) [40.5-75]	Shift in Normality from Baseline to Day 6/Discharge Confinement	Low, NCS to Low, NCS - n (%)	6 (7.5)	1 (2.4)	2 (5.1)	9 (5.6)
		Normal to Low, NCS - n (%)	0	2 (4.9)	2 (5.1)	4 (2.5)
		Normal to Normal - n (%)	72 (90.0)	36 (87.8)	31 (79.5)	139 (86.9)
		High, NCS to Normal - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Neutrophils/Leukocytes (%) [40.5-75]	Day 30	n	76	38	33	147
		Mean (SD)	54.17 (10.505)	54.80 (8.790)	52.12 (7.480)	53.87 (9.460)
		Median	56.45	54.35	51.00	54.30
		Min, Max	29.5, 73.7	37.5, 72.6	39.4, 68.8	29.5, 73.7
		Low value - n (%)	9 (11.3)	1 (2.4)	2 (5.1)	12 (7.5)
		Normal value - n (%)	67 (83.8)	37 (90.2)	31 (79.5)	135 (84.4)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	9 (11.3)	1 (2.4)	2 (5.1)	12 (7.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Neutrophils/Leukocytes (%) [40.5-75]	Change from Baseline to Day 30	n	76	38	33	147
		Mean (SD)	-1.79 (6.222)	-0.63 (8.869)	-3.30 (6.815)	-1.83 (7.132)
		Median	-1.70	-0.25	-3.80	-1.70
		Min, Max	-29.6, 15.3	-21.4, 14.9	-14.9, 10.4	-29.6, 15.3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Neutrophils/Leukocytes (%) [40.5-75]	Shift in Normality from Baseline to Day 30	Low, NCS to Low, NCS - n (%)	5 (6.3)	0	2 (5.1)	7 (4.4)
		Low, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)
		Normal to Low, NCS - n (%)	4 (5.0)	1 (2.4)	0	5 (3.1)
		Normal to Normal - n (%)	65 (81.3)	35 (85.4)	31 (79.5)	131 (81.9)
		High, NCS to Normal - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Neutrophils/Leukocytes (%) [40.5-75]	Day 60	n	74	37	31	142
		Mean (SD)	54.32 (9.025)	54.66 (6.940)	51.70 (8.550)	53.84 (8.446)
		Median	55.40	54.50	52.80	54.20
		Min, Max	32.4, 74.4	33.0, 68.4	36.4, 69.8	32.4, 74.4
		Low value - n (%)	4 (5.0)	2 (4.9)	4 (10.3)	10 (6.3)
		Normal value - n (%)	70 (87.5)	35 (85.4)	27 (69.2)	132 (82.5)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	2 (4.9)	4 (10.3)	10 (6.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Neutrophils/Leukocytes (%) [40.5-75]	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	-1.84 (6.711)	-0.71 (6.303)	-4.00 (7.423)	-2.02 (6.820)
		Median	-2.60	0.40	-3.40	-2.25
		Min, Max	-23.5, 25.9	-18.4, 8.3	-21.7, 12.8	-23.5, 25.9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Neutrophils/Leukocytes (%) [40.5-75]	Shift in Normality from Baseline to Day 60	Low, NCS to Low, NCS - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		Low, NCS to Normal - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		Normal to Low, NCS - n (%)	1 (1.3)	2 (4.9)	3 (7.7)	6 (3.8)
		Normal to Normal - n (%)	67 (83.8)	33 (80.5)	26 (66.7)	126 (78.8)
		High, NCS to Normal - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Neutrophils/Leukocytes (%) [40.5-75]	Day 91/Discharge n Ambulatory		73	36	33	142
		Mean (SD)	59.50 (9.136)	60.99 (6.230)	57.90 (7.449)	59.50 (8.125)
		Median	61.20	60.90	56.50	60.70
		Min, Max	30.7, 77.0	43.6, 72.2	40.1, 74.8	30.7, 77.0
		Low value - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)
		Normal value - n (%)	69 (86.3)	36 (87.8)	32 (82.1)	137 (85.6)
		High value - n (%)	2 (2.5)	0	0	2 (1.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	0	1 (2.6)	5 (3.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Neutrophils/Leukocytes (%) [40.5-75]	Change from Baseline to Day 91/Discharge Ambulatory	n	73	36	33	142
		Mean (SD)	3.82 (8.411)	5.66 (6.807)	2.48 (9.010)	3.97 (8.204)
		Median	2.10	5.75	2.60	2.80
		Min, Max	-24.4, 32.2	-12.4, 17.3	-15.1, 20.1	-24.4, 32.2

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Neutrophils/Leukocytes (%) [40.5-75]	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Low, NCS to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Low, NCS to Normal - n (%)	4 (5.0)	1 (2.4)	2 (5.1)	7 (4.4)
		Normal to Low, NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		Normal to Normal - n (%)	64 (80.0)	34 (82.9)	30 (76.9)	128 (80.0)
		Normal to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to Normal - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		High, NCS to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Lymphocytes/Leuko cytes (%) [15.4-48.5]	Baseline	n	80	41	39	160
		Mean (SD)	35.35 (8.589)	35.89 (7.796)	35.61 (7.879)	35.55 (8.175)
		Median	34.60	36.30	35.80	35.80
		Min, Max	17.6, 58.8	13.1, 53.0	19.0, 49.7	13.1, 58.8
		Low value - n (%)	0	1 (2.4)	0	1 (0.6)
		Normal value - n (%)	74 (92.5)	39 (95.1)	37 (94.9)	150 (93.8)
		High value - n (%)	6 (7.5)	1 (2.4)	2 (5.1)	9 (5.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	6 (7.5)	2 (4.9)	2 (5.1)	10 (6.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Lymphocytes/Leuko cytes (%) [15.4-48.5]	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	35.75 (8.573)	35.91 (7.170)	37.30 (9.625)	36.14 (8.460)
		Median	34.80	34.65	35.40	34.90
		Min, Max	16.8, 62.6	22.3, 51.0	18.2, 65.0	16.8, 65.0
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)
		High value - n (%)	6 (7.5)	3 (7.3)	4 (10.3)	13 (8.1)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	6 (7.5)	3 (7.3)	4 (10.3)	13 (8.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Lymphocytes/Leuko cytes (%) [15.4-48.5]	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	0.40 (5.323)	-0.07 (5.002)	1.45 (5.638)	0.51 (5.309)
		Median	1.00	0.00	1.60	0.80
		Min, Max	-24.0, 16.6	-9.0, 17.8	-16.4, 15.8	-24.0, 17.8

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Lymphocytes/Leuko cytes (%) [15.4-48.5]	Shift in Normality from Baseline to Day 6/Discharge Confinement	Low, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)
		Normal to Normal - n (%)	73 (91.3)	36 (87.8)	31 (79.5)	140 (87.5)
		Normal to High, NCS - n (%)	1 (1.3)	2 (4.9)	2 (5.1)	5 (3.1)
		High, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to High, NCS - n (%)	5 (6.3)	1 (2.4)	2 (5.1)	8 (5.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Lymphocytes/Leuko cytes (%) [15.4-48.5]	Day 30	n	76	38	33	147
		Mean (SD)	36.31 (9.580)	35.74 (8.472)	38.90 (7.158)	36.75 (8.831)
		Median	35.25	34.55	39.90	36.40
		Min, Max	18.0, 59.3	15.3, 50.6	22.9, 50.0	15.3, 59.3
		Low value - n (%)	0	1 (2.4)	0	1 (0.6)
		Normal value - n (%)	68 (85.0)	35 (85.4)	30 (76.9)	133 (83.1)
		High value - n (%)	8 (10.0)	2 (4.9)	3 (7.7)	13 (8.1)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	8 (10.0)	3 (7.3)	3 (7.7)	14 (8.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Lymphocytes/Leuko cytes (%) [15.4-48.5]	Change from Baseline to Day 30	n	76	38	33	147
		Mean (SD)	1.09 (5.983)	0.01 (8.430)	3.05 (6.086)	1.25 (6.757)
		Median	1.25	-0.05	3.70	1.60
		Min, Max	-14.5, 26.8	-17.5, 20.3	-8.9, 13.7	-17.5, 26.8

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Lymphocytes/Leuko cytes (%) [15.4-48.5]	Shift in Normality from Baseline to Day 30	Low, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)
		Normal to Low, NCS - n (%)	0	1 (2.4)	0	1 (0.6)
		Normal to Normal - n (%)	66 (82.5)	33 (80.5)	29 (74.4)	128 (80.0)
		Normal to High, NCS - n (%)	5 (6.3)	2 (4.9)	2 (5.1)	9 (5.6)
		High, NCS to Normal - n (%)	2 (2.5)	1 (2.4)	1 (2.6)	4 (2.5)
		High, NCS to High, NCS - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Lymphocytes/Leuko cytes (%) [15.4-48.5]	Day 60	n	74	37	31	142
		Mean (SD)	36.36 (8.632)	36.66 (6.609)	39.41 (8.609)	37.11 (8.186)
		Median	36.05	35.90	39.00	36.70
		Min, Max	16.8, 56.2	25.9, 58.4	22.2, 54.1	16.8, 58.4
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	67 (83.8)	36 (87.8)	24 (61.5)	127 (79.4)
		High value - n (%)	7 (8.8)	1 (2.4)	7 (17.9)	15 (9.4)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	7 (8.8)	1 (2.4)	7 (17.9)	15 (9.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Lymphocytes/Leuko cytes (%) [15.4-48.5]	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	1.37 (6.691)	0.90 (6.077)	3.75 (6.670)	1.76 (6.574)
		Median	1.35	0.50	3.50	1.50
		Min, Max	-24.2, 26.3	-12.5, 17.9	-13.6, 21.7	-24.2, 26.3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Lymphocytes/Leuko cytes (%) [15.4-48.5]	Shift in Normality from Baseline to Day 60	Low, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)
		Normal to Normal - n (%)	65 (81.3)	34 (82.9)	24 (61.5)	123 (76.9)
		Normal to High, NCS - n (%)	5 (6.3)	1 (2.4)	5 (12.8)	11 (6.9)
		High, NCS to Normal - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		High, NCS to High, NCS - n (%)	2 (2.5)	0	2 (5.1)	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Lymphocytes/Leuko cytes (%) [15.4-48.5]	Day 91/Discharge n Ambulatory		73	36	33	142
		Mean (SD)	31.75 (8.125)	30.26 (6.001)	33.80 (7.920)	31.85 (7.643)
		Median	30.80	29.50	33.30	31.25
		Min, Max	13.2, 56.4	19.2, 45.1	17.4, 52.6	13.2, 56.4
		Low value - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value - n (%)	70 (87.5)	36 (87.8)	31 (79.5)	137 (85.6)
		High value - n (%)	2 (2.5)	0	2 (5.1)	4 (2.5)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	0	2 (5.1)	5 (3.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Lymphocytes/Leuko cytes (%) [15.4-48.5]	Change from Baseline to Day 91/Discharge Ambulatory	n	73	36	33	142
		Mean (SD)	-3.67 (7.700)	-5.66 (6.483)	-2.06 (8.268)	-3.80 (7.604)
		Median	-3.00	-6.05	-1.90	-3.35
		Min, Max	-28.1, 22.3	-16.8, 10.7	-17.8, 15.1	-28.1, 22.3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Lymphocytes/Leukocytes (%) [15.4-48.5]	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Low, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)
		Normal to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	66 (82.5)	34 (82.9)	30 (76.9)	130 (81.3)
		Normal to High, NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		High, NCS to Normal - n (%)	4 (5.0)	1 (2.4)	1 (2.6)	6 (3.8)
		High, NCS to High, NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Monocytes/Leukocytes (%) [2.6-10.1]	Baseline	n	80	41	39	160
		Mean (SD)	5.48 (1.636)	5.43 (1.605)	5.33 (1.316)	5.43 (1.548)
		Median	5.20	5.20	5.30	5.20
		Min, Max	2.5, 12.3	2.9, 10.0	2.8, 8.8	2.5, 12.3
		Low value - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value - n (%)	78 (97.5)	41 (100)	39 (100)	158 (98.8)
		High value - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Monocytes/Leukocytes (%) [2.6-10.1]	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	6.12 (1.363)	5.68 (1.470)	5.99 (1.438)	5.98 (1.411)
		Median	6.00	5.50	5.70	5.90
		Min, Max	3.3, 11.1	2.9, 9.9	3.3, 9.8	2.9, 11.1
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		High value - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Monocytes/Leukocytes (%) [2.6-10.1]	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	0.64 (1.302)	0.24 (1.590)	0.76 (1.212)	0.56 (1.368)
		Median	0.70	0.40	0.90	0.70
		Min, Max	-3.8, 3.8	-7.0, 3.0	-2.0, 3.8	-7.0, 3.8

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Monocytes/Leukocytes (%) [2.6-10.1]	Shift in Normality from Baseline to Day 6/Discharge Confinement	Low, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	77 (96.3)	40 (97.6)	35 (89.7)	152 (95.0)
		Normal to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Monocytes/Leukocytes (%) [2.6-10.1]	Day 30	n	76	38	33	147
		Mean (SD)	6.09 (1.940)	5.76 (1.081)	5.62 (1.450)	5.90 (1.653)
		Median	5.70	5.70	5.70	5.70
		Min, Max	2.9, 15.0	3.7, 7.6	2.8, 8.8	2.8, 15.0
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	38 (92.7)	33 (84.6)	145 (90.6)
		High value - n (%)	2 (2.5)	0	0	2 (1.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Monocytes/Leukocytes (%) [2.6-10.1]	Change from Baseline to Day 30	n	76	38	33	147
		Mean (SD)	0.60 (1.304)	0.37 (1.261)	0.38 (1.421)	0.49 (1.316)
		Median	0.50	0.35	0.20	0.50
		Min, Max	-2.2, 3.6	-3.5, 3.7	-1.9, 4.9	-3.5, 4.9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Monocytes/Leukocytes (%) [2.6-10.1]	Shift in Normality from Baseline to Day 30	Low, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	73 (91.3)	38 (92.7)	33 (84.6)	144 (90.0)
		Normal to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Monocytes/Leukocytes (%) [2.6-10.1]	Day 60	n	74	37	31	142
		Mean (SD)	6.05 (2.015)	5.42 (1.468)	5.44 (1.701)	5.75 (1.835)
		Median	5.85	5.30	5.50	5.65
		Min, Max	2.0, 13.3	2.9, 8.3	2.4, 9.4	2.0, 13.3
		Low value - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		Normal value - n (%)	68 (85.0)	37 (90.2)	30 (76.9)	135 (84.4)
		High value - n (%)	3 (3.8)	0	0	3 (1.9)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	6 (7.5)	0	1 (2.6)	7 (4.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Monocytes/Leukocytes (%) [2.6-10.1]	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	0.57 (1.957)	-0.05 (1.649)	0.37 (1.691)	0.36 (1.831)
		Median	0.50	0.30	0.10	0.35
		Min, Max	-4.1, 7.1	-7.1, 2.8	-4.4, 3.3	-7.1, 7.1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Monocytes/Leukocytes (%) [2.6-10.1]	Shift in Normality from Baseline to Day 60	Low, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		Normal to Normal - n (%)	66 (82.5)	37 (90.2)	30 (76.9)	133 (83.1)
		Normal to High, NCS - n (%)	3 (3.8)	0	0	3 (1.9)
		High, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Monocytes/Leukocytes (%) [2.6-10.1]	Day 91/Discharge n Ambulatory		73	36	33	142
		Mean (SD)	5.88 (1.969)	5.79 (1.462)	5.54 (1.954)	5.78 (1.842)
		Median	5.60	5.95	5.50	5.70
		Min, Max	2.5, 11.8	2.9, 10.3	2.0, 10.4	2.0, 11.8
		Low value - n (%)	1 (1.3)	0	2 (5.1)	3 (1.9)
		Normal value - n (%)	70 (87.5)	35 (85.4)	30 (76.9)	135 (84.4)
		High value - n (%)	2 (2.5)	1 (2.4)	1 (2.6)	4 (2.5)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	1 (2.4)	3 (7.7)	7 (4.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Monocytes/Leukocytes (%) [2.6-10.1]	Change from Baseline to Day 91/Discharge Ambulatory	n	73	36	33	142
		Mean (SD)	0.37 (1.565)	0.33 (1.251)	0.30 (1.950)	0.35 (1.582)
		Median	0.40	0.60	0.30	0.40
		Min, Max	-3.1, 6.5	-3.3, 2.7	-5.6, 4.8	-5.6, 6.5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Monocytes/Leukocytes (%) [2.6-10.1]	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Low, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n (%)	1 (1.3)	0	2 (5.1)	3 (1.9)
		Normal to Normal - n (%)	69 (86.3)	35 (85.4)	30 (76.9)	134 (83.8)
		Normal to High, NCS - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		High, NCS to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Eosinophils/Leukocytes (%) [0-6.8]	Baseline	n	80	41	39	160
		Mean (SD)	2.77 (1.219)	2.87 (1.354)	2.79 (1.644)	2.80 (1.359)
		Median	2.60	2.70	2.60	2.60
		Min, Max	0.5, 6.3	1.0, 6.4	0.5, 8.3	0.5, 8.3
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	38 (97.4)	159 (99.4)
		High value - n (%)	0	0	1 (2.6)	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Eosinophils/Leukocytes (%) [0-6.8]	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	2.60 (1.380)	2.87 (1.553)	2.77 (1.676)	2.70 (1.491)
		Median	2.35	2.65	2.50	2.40
		Min, Max	0.9, 8.9	0.7, 9.1	0.9, 8.0	0.7, 9.1
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	79 (98.8)	39 (95.1)	34 (87.2)	152 (95.0)
		High value - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Eosinophils/Leukocytes (%) [0-6.8]	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	-0.17 (0.861)	0.02 (0.860)	-0.08 (0.991)	-0.10 (0.889)
		Median	-0.10	-0.10	-0.20	-0.10
		Min, Max	-2.4, 3.7	-2.5, 2.7	-2.7, 3.1	-2.7, 3.7

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Eosinophils/Leukocytes (%) [0-6.8]	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Normal - n (%)	79 (98.8)	39 (95.1)	34 (87.2)	152 (95.0)
		Normal to High, NCS - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		High, NCS to High, NCS - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Eosinophils/Leukocytes (%) [0-6.8]	Day 30	n	76	38	33	147
		Mean (SD)	2.74 (1.303)	3.01 (1.499)	2.68 (1.406)	2.80 (1.375)
		Median	2.65	2.65	2.50	2.60
		Min, Max	0.9, 6.6	0.6, 7.1	0.3, 7.4	0.3, 7.4
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	76 (95.0)	37 (90.2)	32 (82.1)	145 (90.6)
		High value - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Eosinophils/Leukocytes (%) [0-6.8]	Change from Baseline to Day 30	n	76	38	33	147
		Mean (SD)	0.02 (0.952)	0.10 (1.031)	-0.13 (1.393)	0.01 (1.080)
		Median	0.00	0.05	0.00	0.00
		Min, Max	-2.2, 2.8	-2.1, 3.4	-4.3, 3.0	-4.3, 3.4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Eosinophils/Leukocytes (%) [0-6.8]	Shift in Normality from Baseline to Day 30	Normal to Normal - n (%)	76 (95.0)	37 (90.2)	31 (79.5)	144 (90.0)
		Normal to High, NCS - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
		High, NCS to Normal - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Eosinophils/Leukocytes (%) [0-6.8]	Day 60	n	74	37	31	142
		Mean (SD)	2.52 (1.228)	2.64 (1.695)	2.73 (1.424)	2.60 (1.398)
		Median	2.20	2.20	2.50	2.20
		Min, Max	0.7, 6.4	0.8, 9.1	0.8, 7.1	0.7, 9.1
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	36 (87.8)	30 (76.9)	140 (87.5)
		High value - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Eosinophils/Leukocytes (%) [0-6.8]	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	-0.22 (0.948)	-0.14 (1.089)	-0.15 (1.168)	-0.19 (1.029)
		Median	-0.10	-0.10	-0.10	-0.10
		Min, Max	-2.7, 1.9	-2.1, 5.0	-2.8, 2.3	-2.8, 5.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Eosinophils/Leukocytes (%) [0-6.8]	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	74 (92.5)	36 (87.8)	29 (74.4)	139 (86.9)
		Normal to High, NCS - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
		High, NCS to Normal - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Eosinophils/Leukocytes (%) [0-6.8]	Day 91/Discharge n Ambulatory		73	36	33	142
		Mean (SD)	2.23 (1.239)	2.28 (1.043)	2.16 (1.278)	2.23 (1.195)
		Median	1.90	1.95	2.00	2.00
		Min, Max	0.3, 6.5	0.6, 5.5	0.0, 5.5	0.0, 6.5
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	73 (91.3)	36 (87.8)	33 (84.6)	142 (88.8)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Eosinophils/Leukocytes (%) [0-6.8]	Change from Baseline to Day 91/Discharge Ambulatory	n	73	36	33	142
		Mean (SD)	-0.55 (1.035)	-0.41 (0.764)	-0.65 (1.502)	-0.54 (1.100)
		Median	-0.50	-0.45	-0.60	-0.50
		Min, Max	-3.2, 2.6	-1.9, 1.8	-3.9, 4.4	-3.9, 4.4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Eosinophils/Leukocytes (%) [0-6.8]	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Normal - n (%)	73 (91.3)	36 (87.8)	32 (82.1)	141 (88.1)
		High, NCS to Normal - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Basophils/Leukocytes (%) [0-2]	Baseline	n	80	41	39	160
		Mean (SD)	0.61 (0.295)	0.60 (0.258)	0.64 (0.340)	0.62 (0.296)
		Median	0.60	0.60	0.60	0.60
		Min, Max	0.1, 1.8	0.2, 1.4	0.3, 2.3	0.1, 2.3
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	38 (97.4)	159 (99.4)
		High value - n (%)	0	0	1 (2.6)	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Basophils/Leukocytes (%) [0-2]	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	0.64 (0.287)	0.63 (0.216)	0.68 (0.302)	0.65 (0.273)
		Median	0.60	0.60	0.60	0.60
		Min, Max	0.1, 2.0	0.3, 1.4	0.2, 1.8	0.1, 2.0
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Basophils/Leukocytes (%) [0-2]	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	0.03 (0.331)	0.04 (0.210)	0.02 (0.408)	0.03 (0.323)
		Median	0.00	0.05	0.00	0.00
		Min, Max	-1.2, 1.1	-0.6, 0.6	-1.4, 1.5	-1.4, 1.5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Basophils/Leukocytes (%) [0-2]	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Normal - n (%)	80 (100)	40 (97.6)	34 (87.2)	154 (96.3)
		High, NCS to Normal - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Basophils/Leukocytes (%) [0-2]	Day 30	n	76	38	33	147
		Mean (SD)	0.68 (0.324)	0.68 (0.286)	0.67 (0.405)	0.68 (0.332)
		Median	0.60	0.70	0.60	0.60
		Min, Max	0.0, 1.9	0.2, 1.5	0.3, 2.5	0.0, 2.5
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	76 (95.0)	38 (92.7)	32 (82.1)	146 (91.3)
		High value - n (%)	0	0	1 (2.6)	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Basophils/Leukocytes (%) [0-2]	Change from Baseline to Day 30	n	76	38	33	147
		Mean (SD)	0.07 (0.278)	0.13 (0.292)	0.01 (0.449)	0.07 (0.327)
		Median	0.10	0.10	0.00	0.10
		Min, Max	-1.1, 0.8	-0.3, 0.9	-1.6, 1.4	-1.6, 1.4

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Basophils/Leukocytes (%) [0-2]	Shift in Normality from Baseline to Day 30	Normal to Normal - n (%)	76 (95.0)	38 (92.7)	31 (79.5)	145 (90.6)
		Normal to High, NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		High, NCS to Normal - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Basophils/Leukocytes (%) [0-2]	Day 60	n	74	37	31	142
		Mean (SD)	0.72 (0.516)	0.63 (0.238)	0.71 (0.332)	0.69 (0.421)
		Median	0.60	0.60	0.70	0.60
		Min, Max	0.0, 4.1	0.3, 1.1	0.2, 1.7	0.0, 4.1
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	73 (91.3)	37 (90.2)	31 (79.5)	141 (88.1)
		High value - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Basophils/Leukocytes (%) [0-2]	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	0.11 (0.512)	0.01 (0.215)	0.04 (0.460)	0.07 (0.441)
		Median	0.05	0.00	0.10	0.05
		Min, Max	-0.8, 3.5	-0.5, 0.4	-1.6, 1.0	-1.6, 3.5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Basophils/Leukocytes (%) [0-2]	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	73 (91.3)	37 (90.2)	30 (76.9)	140 (87.5)
		Normal to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to Normal - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Basophils/Leukocytes (%) [0-2]	Day 91/Discharge n Ambulatory		73	36	33	142
		Mean (SD)	0.64 (0.255)	0.68 (0.342)	0.60 (0.328)	0.64 (0.296)
		Median	0.60	0.60	0.50	0.60
		Min, Max	0.2, 1.2	0.3, 2.1	0.0, 1.7	0.0, 2.1
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	73 (91.3)	35 (85.4)	33 (84.6)	141 (88.1)
		High value - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Basophils/Leukocytes (%) [0-2]	Change from Baseline to Day 91/Discharge Ambulatory	n	73	36	33	142
		Mean (SD)	0.02 (0.300)	0.07 (0.368)	-0.06 (0.430)	0.02 (0.352)
		Median	0.00	0.00	-0.10	0.00
		Min, Max	-1.2, 0.5	-0.5, 1.6	-1.8, 0.7	-1.8, 1.6

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Basophils/Leukocytes (%) [0-2]	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Normal - n (%)	73 (91.3)	35 (85.4)	32 (82.1)	140 (87.5)
		Normal to High, NCS - n (%)	0	1 (2.4)	0	1 (0.6)
		High, NCS to Normal - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Baseline	n	80	41	39	160
		Mean (SD)	275.1 (64.60)	290.4 (68.57)	287.3 (90.52)	282.0 (72.55)
		Median	257.0	290.0	269.0	274.5
		Min, Max	111, 482	187, 537	141, 563	111, 563
		Low value - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value - n (%)	76 (95.0)	39 (95.1)	35 (89.7)	150 (93.8)
		High value - n (%)	3 (3.8)	2 (4.9)	4 (10.3)	9 (5.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	2 (4.9)	4 (10.3)	10 (6.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Baseline	Platelets Decrease				
		Grade 0 - n (%)	79 (98.8)	41 (100)	39 (100)	159 (99.4)
		Grade 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	282.1 (66.40)	291.0 (80.27)	279.6 (82.97)	283.9 (73.70)
		Median	273.0	277.0	278.0	276.0
		Min, Max	151, 466	184, 566	162, 545	151, 566
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	75 (93.8)	36 (87.8)	32 (82.1)	143 (89.4)
		High value - n (%)	5 (6.3)	4 (9.8)	3 (7.7)	12 (7.5)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	5 (6.3)	4 (9.8)	3 (7.7)	12 (7.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Day 6/Discharge Confinement	Platelets Decrease				
		Grade 0 - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	7.0 (35.80)	0.7 (35.09)	-10.0 (48.20)	1.5 (39.09)
		Median	3.5	4.0	-10.0	3.0
		Min, Max	-88, 116	-84, 126	-158, 100	-158, 126

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Low, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	73 (91.3)	36 (87.8)	30 (76.9)	139 (86.9)
		Normal to High, NCS - n (%)	3 (3.8)	2 (4.9)	1 (2.6)	6 (3.8)
		High, NCS to Normal - n (%)	1 (1.3)	0	2 (5.1)	3 (1.9)
		High, NCS to High, NCS - n (%)	2 (2.5)	2 (4.9)	2 (5.1)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	Platelets Decrease				
		0 to 0 - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		1 to 0 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Day 30	n	75	38	33	146
		Mean (SD)	278.4 (71.21)	271.8 (65.35)	276.3 (90.53)	276.2 (74.12)
		Median	263.0	267.0	256.0	264.0
		Min, Max	118, 543	172, 442	160, 522	118, 543
		Low value - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value - n (%)	69 (86.3)	35 (85.4)	30 (76.9)	134 (83.8)
		High value - n (%)	5 (6.3)	3 (7.3)	3 (7.7)	11 (6.9)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	6 (7.5)	3 (7.3)	3 (7.7)	12 (7.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Day 30	Platelets Decrease				
		Grade 0 - n (%)	74 (92.5)	38 (92.7)	33 (84.6)	145 (90.6)
		Grade 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Change from Baseline to Day 30	n	75	38	33	146
		Mean (SD)	2.8 (41.21)	-18.6 (35.17)	-10.9 (43.14)	-5.9 (40.99)
		Median	4.0	-14.5	-13.0	-6.5
		Min, Max	-98, 150	-106, 70	-110, 97	-110, 150

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Shift in Normality from Baseline to Day 30	Low, NCS to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	69 (86.3)	35 (85.4)	28 (71.8)	132 (82.5)
		Normal to High, NCS - n (%)	3 (3.8)	1 (2.4)	1 (2.6)	5 (3.1)
		High, NCS to Normal - n (%)	0	0	2 (5.1)	2 (1.3)
		High, NCS to High, NCS - n (%)	2 (2.5)	2 (4.9)	2 (5.1)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Shift in Toxicity from Baseline to Day 30	Platelets Decrease				
		0 to 0 - n (%)	74 (92.5)	38 (92.7)	33 (84.6)	145 (90.6)
		1 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Day 60	n	74	37	31	142
		Mean (SD)	258.1 (59.96)	259.9 (58.60)	262.5 (78.87)	259.6 (63.76)
		Median	246.0	250.0	239.0	247.0
		Min, Max	128, 410	167, 421	133, 489	128, 489
		Low value - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		Normal value - n (%)	71 (88.8)	35 (85.4)	28 (71.8)	134 (83.8)
		High value - n (%)	2 (2.5)	2 (4.9)	2 (5.1)	6 (3.8)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	2 (4.9)	3 (7.7)	8 (5.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Day 60	Platelets Decrease				
		Grade 0 - n (%)	73 (91.3)	37 (90.2)	30 (76.9)	140 (87.5)
		Grade 1 - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	-17.6 (35.92)	-34.3 (38.45)	-27.5 (53.25)	-24.1 (41.24)
		Median	-13.5	-34.0	-15.0	-19.0
		Min, Max	-140, 55	-131, 36	-186, 98	-186, 98

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Shift in Normality from Baseline to Day 60	Low, NCS to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal to Normal - n (%)	69 (86.3)	35 (85.4)	25 (64.1)	129 (80.6)
		Normal to High, NCS - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)
		High, NCS to Normal - n (%)	2 (2.5)	0	3 (7.7)	5 (3.1)
		High, NCS to High, NCS - n (%)	0	2 (4.9)	1 (2.6)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Shift in Toxicity from Baseline to Day 60	Platelets Decrease				
		0 to 0 - n (%)	73 (91.3)	37 (90.2)	30 (76.9)	140 (87.5)
		0 to 1 - n (%)	0	0	1 (2.6)	1 (0.6)
		1 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Day 91/Discharge n Ambulatory		72	36	33	141
		Mean (SD)	250.8 (66.74)	262.8 (94.26)	263.2 (80.83)	256.8 (77.53)
		Median	246.0	250.5	263.0	249.0
		Min, Max	93, 443	164, 713	137, 451	93, 713
		Low value - n (%)	4 (5.0)	0	1 (2.6)	5 (3.1)
		Normal value - n (%)	65 (81.3)	34 (82.9)	29 (74.4)	128 (80.0)
		High value - n (%)	3 (3.8)	2 (4.9)	3 (7.7)	8 (5.0)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	7 (8.8)	2 (4.9)	4 (10.3)	13 (8.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Day 91/Discharge Ambulatory	Platelets Decrease				
		Grade 0 - n (%)	68 (85.0)	36 (87.8)	32 (82.1)	136 (85.0)
		Grade 1 - n (%)	4 (5.0)	0	1 (2.6)	5 (3.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Change from Baseline to Day 91/Discharge Ambulatory	n	72	36	33	141
		Mean (SD)	-24.7 (38.19)	-33.9 (49.49)	-24.0 (52.64)	-26.9 (44.75)
		Median	-21.0	-35.5	-19.0	-22.0
		Min, Max	-165, 107	-123, 176	-136, 96	-165, 176

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Low, NCS to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		Normal to Normal - n (%)	62 (77.5)	34 (82.9)	27 (69.2)	123 (76.9)
		Normal to High, NCS - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		High, NCS to Normal - n (%)	3 (3.8)	0	2 (5.1)	5 (3.1)
		High, NCS to High, NCS - n (%)	0	2 (4.9)	2 (5.1)	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Platelets (GI/L)	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	Platelets Decrease				
		0 to 0 - n (%)	68 (85.0)	36 (87.8)	32 (82.1)	136 (85.0)
		0 to 1 - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		1 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [26-34]	Baseline	n	80	41	39	160
		Mean (SD)	30.19 (1.930)	30.39 (2.048)	29.74 (2.468)	30.13 (2.102)
		Median	30.00	31.00	31.00	30.00
		Min, Max	24.0, 34.0	23.0, 35.0	23.0, 33.0	23.0, 35.0
		Low value - n (%)	2 (2.5)	1 (2.4)	4 (10.3)	7 (4.4)
		Normal value - n (%)	78 (97.5)	39 (95.1)	35 (89.7)	152 (95.0)
		High value - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	2 (4.9)	4 (10.3)	8 (5.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [26-34]	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	30.28 (2.038)	30.55 (2.088)	29.43 (2.513)	30.15 (2.190)
		Median	30.00	31.00	30.00	30.00
		Min, Max	24.0, 34.0	24.0, 37.0	22.0, 33.0	22.0, 37.0
		Low value - n (%)	3 (3.8)	1 (2.4)	4 (10.3)	8 (5.0)
		Normal value - n (%)	77 (96.3)	38 (92.7)	31 (79.5)	146 (91.3)
		High value - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	2 (4.9)	4 (10.3)	9 (5.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [26-34]	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	0.09 (0.799)	0.23 (0.734)	-0.11 (0.632)	0.08 (0.752)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-2.0, 2.0	-1.0, 2.0	-1.0, 1.0	-2.0, 2.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [26-34]	Shift in Normality from Baseline to Day 6/Discharge Confinement	Low, NCS to Low, NCS - n (%)	2 (2.5)	1 (2.4)	4 (10.3)	7 (4.4)
		Normal to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	77 (96.3)	38 (92.7)	31 (79.5)	146 (91.3)
		High, NCS to High, NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [26-34]	Day 30	n	76	38	33	147
		Mean (SD)	30.04 (2.075)	30.29 (2.265)	29.45 (2.729)	29.97 (2.288)
		Median	30.50	30.50	30.00	30.00
		Min, Max	22.0, 34.0	23.0, 36.0	23.0, 34.0	22.0, 36.0
		Low value - n (%)	2 (2.5)	1 (2.4)	4 (10.3)	7 (4.4)
		Normal value - n (%)	74 (92.5)	36 (87.8)	29 (74.4)	139 (86.9)
		High value - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	2 (4.9)	4 (10.3)	8 (5.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [26-34]	Change from Baseline to Day 30	n	76	38	33	147
		Mean (SD)	-0.16 (0.881)	-0.05 (0.804)	-0.06 (0.705)	-0.11 (0.821)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-2.0, 2.0	-2.0, 1.0	-1.0, 2.0	-2.0, 2.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [26-34]	Shift in Normality from Baseline to Day 30	Low, NCS to Low, NCS - n (%)	2 (2.5)	1 (2.4)	4 (10.3)	7 (4.4)
		Normal to Normal - n (%)	74 (92.5)	36 (87.8)	29 (74.4)	139 (86.9)
		High, NCS to High, NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [26-34]	Day 60	n	74	37	31	142
		Mean (SD)	29.72 (2.237)	30.35 (2.288)	29.55 (2.657)	29.85 (2.350)
		Median	30.00	31.00	30.00	30.00
		Min, Max	21.0, 34.0	23.0, 35.0	22.0, 33.0	21.0, 35.0
		Low value - n (%)	4 (5.0)	1 (2.4)	3 (7.7)	8 (5.0)
		Normal value - n (%)	70 (87.5)	35 (85.4)	28 (71.8)	133 (83.1)
		High value - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	2 (4.9)	3 (7.7)	9 (5.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [26-34]	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	-0.45 (0.909)	-0.05 (1.053)	-0.23 (0.717)	-0.30 (0.921)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-3.0, 3.0	-2.0, 2.0	-1.0, 1.0	-3.0, 3.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [26-34]	Shift in Normality from Baseline to Day 60	Low, NCS to Low, NCS - n (%)	2 (2.5)	1 (2.4)	3 (7.7)	6 (3.8)
		Normal to Low, NCS - n (%)	2 (2.5)	0	0	2 (1.3)
		Normal to Normal - n (%)	70 (87.5)	35 (85.4)	28 (71.8)	133 (83.1)
		High, NCS to High, NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [26-34]	Day 91/Discharge n Ambulatory		73	36	33	142
		Mean (SD)	29.52 (2.292)	30.03 (2.274)	29.42 (2.840)	29.63 (2.420)
		Median	30.00	31.00	30.00	30.00
		Min, Max	21.0, 34.0	23.0, 35.0	21.0, 33.0	21.0, 35.0
		Low value - n (%)	4 (5.0)	1 (2.4)	4 (10.3)	9 (5.6)
		Normal value - n (%)	69 (86.3)	34 (82.9)	29 (74.4)	132 (82.5)
		High value - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	4 (5.0)	2 (4.9)	4 (10.3)	10 (6.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [26-34]	Change from Baseline to Day 91/Discharge Ambulatory	n	73	36	33	142
		Mean (SD)	-0.59 (1.012)	-0.42 (1.131)	-0.09 (0.766)	-0.43 (1.007)
		Median	-1.00	0.00	0.00	0.00
		Min, Max	-3.0, 3.0	-3.0, 2.0	-2.0, 1.0	-3.0, 3.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular Hemoglobin (pg) [26-34]	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Low, NCS to Low, NCS - n (%)	2 (2.5)	1 (2.4)	4 (10.3)	7 (4.4)
		Normal to Low, NCS - n (%)	2 (2.5)	0	0	2 (1.3)
		Normal to Normal - n (%)	69 (86.3)	34 (82.9)	29 (74.4)	132 (82.5)
		High, NCS to High, NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL) [31-38]	Baseline	n	79	41	39	159
		Mean (SD)	33.05 (1.143)	33.10 (1.068)	33.05 (1.235)	33.06 (1.141)
		Median	33.00	33.00	33.00	33.00
		Min, Max	30.0, 35.0	30.0, 35.0	30.0, 36.0	30.0, 36.0
		Low value - n (%)	1 (1.3)	1 (2.4)	2 (5.1)	4 (2.5)
		Normal value - n (%)	78 (97.5)	40 (97.6)	37 (94.9)	155 (96.9)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	1 (2.4)	2 (5.1)	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL) [31-38]	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	33.33 (1.271)	33.50 (1.110)	33.17 (1.151)	33.34 (1.203)
		Median	33.00	34.00	33.00	33.00
		Min, Max	30.0, 36.0	31.0, 36.0	30.0, 35.0	30.0, 36.0
		Low value - n (%)	2 (2.5)	0	2 (5.1)	4 (2.5)
		Normal value - n (%)	78 (97.5)	40 (97.6)	33 (84.6)	151 (94.4)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	0	2 (5.1)	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL) [31-38]	Change from Baseline to Day 6/Discharge Confinement	n	79	40	35	154
		Mean (SD)	0.28 (0.960)	0.40 (0.956)	0.17 (0.891)	0.29 (0.941)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-2.0, 3.0	-1.0, 3.0	-1.0, 2.0	-2.0, 3.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL) [31-38]	Shift in Normality from Baseline to Day 6/Discharge Confinement	Low, NCS to Low, NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		Low, NCS to Normal - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
		Normal to Low, NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		Normal to Normal - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL) [31-38]	Day 30	n	75	36	32	143
		Mean (SD)	32.69 (1.284)	32.89 (1.166)	32.75 (1.136)	32.76 (1.218)
		Median	32.00	33.00	33.00	33.00
		Min, Max	29.0, 35.0	30.0, 35.0	31.0, 35.0	29.0, 35.0
		Low value - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		Normal value - n (%)	72 (90.0)	35 (85.4)	32 (82.1)	139 (86.9)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL) 30 [31-38]	Change from Baseline to Day	n	74	36	32	142
		Mean (SD)	-0.34 (1.264)	-0.28 (0.945)	-0.22 (1.238)	-0.30 (1.178)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-3.0, 2.0	-2.0, 2.0	-2.0, 2.0	-3.0, 2.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Appendix 15.3.6.7

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL) [31-38]	Shift in Normality from Baseline to Day 30	Low, NCS to Low, NCS - n (%)	0	1 (2.4)	0	1 (0.6)
		Low, NCS to Normal - n (%)	1 (1.3)	0	2 (5.1)	3 (1.9)
		Normal to Low, NCS - n (%)	2 (2.5)	0	0	2 (1.3)
		Normal to Normal - n (%)	71 (88.8)	35 (85.4)	30 (76.9)	136 (85.0)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL) [31-38]	Day 60	n	74	37	31	142
		Mean (SD)	32.14 (1.398)	32.59 (1.384)	32.19 (1.377)	32.27 (1.394)
		Median	32.00	33.00	33.00	32.00
		Min, Max	27.0, 35.0	29.0, 35.0	28.0, 34.0	27.0, 35.0
		Low value - n (%)	7 (8.8)	3 (7.3)	3 (7.7)	13 (8.1)
		Normal value - n (%)	67 (83.8)	34 (82.9)	28 (71.8)	129 (80.6)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	7 (8.8)	3 (7.3)	3 (7.7)	13 (8.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Appendix 15.3.6.7

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL) 60 [31-38]	Change from Baseline to Day	n	73	37	31	141
		Mean (SD)	-0.89 (1.298)	-0.46 (1.070)	-0.87 (1.259)	-0.77 (1.239)
		Median	-1.00	-1.00	-1.00	-1.00
		Min, Max	-4.0, 2.0	-2.0, 2.0	-3.0, 2.0	-4.0, 2.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Appendix 15.3.6.7

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL) [31-38]	Shift in Normality from Baseline to Day 60	Low, NCS to Low, NCS - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
		Low, NCS to Normal - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		Normal to Low, NCS - n (%)	7 (8.8)	2 (4.9)	2 (5.1)	11 (6.9)
		Normal to Normal - n (%)	65 (81.3)	34 (82.9)	27 (69.2)	126 (78.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL) [31-38]	Day 91/Discharge n Ambulatory		73	35	33	141
		Mean (SD)	32.14 (1.503)	32.43 (1.461)	32.52 (1.417)	32.30 (1.473)
		Median	32.00	33.00	33.00	32.00
		Min, Max	27.0, 35.0	30.0, 35.0	29.0, 34.0	27.0, 35.0
		Low value - n (%)	10 (12.5)	5 (12.2)	5 (12.8)	20 (12.5)
		Normal value - n (%)	63 (78.8)	30 (73.2)	28 (71.8)	121 (75.6)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	10 (12.5)	5 (12.2)	5 (12.8)	20 (12.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL) [31-38]	Change from Baseline to Day 91/Discharge Ambulatory	n	72	35	33	140
		Mean (SD)	-0.89 (1.194)	-0.66 (1.371)	-0.45 (1.149)	-0.73 (1.235)
		Median	-1.00	-1.00	0.00	-1.00
		Min, Max	-4.0, 2.0	-4.0, 2.0	-3.0, 2.0	-4.0, 2.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. Mean Corpuscular HGB Concentration (g/dL) [31-38]	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Low, NCS to Low, NCS - n (%)	0	1 (2.4)	2 (5.1)	3 (1.9)
		Low, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Low, NCS - n (%)	10 (12.5)	4 (9.8)	3 (7.7)	17 (10.6)
		Normal to Normal - n (%)	61 (76.3)	30 (73.2)	28 (71.8)	119 (74.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. mean corpuscular volume (fL)	Baseline	n	79	41	39	159
		Mean (SD)	91.3 (4.97)	91.6 (4.86)	89.9 (6.07)	91.0 (5.24)
		Median	92.0	92.0	92.0	92.0
		Min, Max	77, 102	77, 103	74, 98	74, 103
		Low value - n (%)	1 (1.3)	1 (2.4)	2 (5.1)	4 (2.5)
		Normal value - n (%)	72 (90.0)	36 (87.8)	36 (92.3)	144 (90.0)
		High value - n (%)	6 (7.5)	4 (9.8)	1 (2.6)	11 (6.9)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	7 (8.8)	5 (12.2)	3 (7.7)	15 (9.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.7

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. mean corpuscular volume (fL)	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	90.8 (5.12)	91.1 (5.41)	88.9 (5.82)	90.4 (5.39)
		Median	90.5	91.5	90.0	91.0
		Min, Max	77, 102	77, 105	74, 100	74, 105
		Low value - n (%)	2 (2.5)	1 (2.4)	2 (5.1)	5 (3.1)
		Normal value - n (%)	70 (87.5)	35 (85.4)	32 (82.1)	137 (85.6)
		High value - n (%)	8 (10.0)	4 (9.8)	1 (2.6)	13 (8.1)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	10 (12.5)	5 (12.2)	3 (7.7)	18 (11.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. mean corpuscular volume (fL)	Change from Baseline to Day 6/Discharge Confinement	n	79	40	35	154
		Mean (SD)	-0.4 (2.08)	-0.4 (1.47)	-0.6 (1.62)	-0.5 (1.83)
		Median	0.0	0.0	0.0	0.0
		Min, Max	-7, 5	-3, 3	-5, 2	-7, 5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.7

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. mean corpuscular volume (fL)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Low, NCS to Low, NCS - n (%)	1 (1.3)	1 (2.4)	2 (5.1)	4 (2.5)
		Normal to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	69 (86.3)	34 (82.9)	32 (82.1)	135 (84.4)
		Normal to High, NCS - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		High, NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)
		High, NCS to High, NCS - n (%)	6 (7.5)	3 (7.3)	1 (2.6)	10 (6.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. mean corpuscular volume (fL)	Day 30	n	75	36	32	143
		Mean (SD)	91.9 (5.10)	92.6 (5.62)	89.8 (6.79)	91.6 (5.70)
		Median	92.0	93.0	91.5	92.0
		Min, Max	77, 102	77, 108	72, 99	72, 108
		Low value - n (%)	1 (1.3)	1 (2.4)	3 (7.7)	5 (3.1)
		Normal value - n (%)	62 (77.5)	29 (70.7)	26 (66.7)	117 (73.1)
		High value - n (%)	12 (15.0)	6 (14.6)	3 (7.7)	21 (13.1)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	13 (16.3)	7 (17.1)	6 (15.4)	26 (16.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. mean corpuscular volume (fL)	Change from Baseline to Day 30	n	74	36	32	142
		Mean (SD)	0.6 (2.08)	0.8 (2.41)	0.4 (2.41)	0.6 (2.23)
		Median	1.0	1.0	0.5	1.0
		Min, Max	-4, 6	-4, 5	-4, 6	-4, 6

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. mean corpuscular volume (fL)	Shift in Normality from Baseline to Day 30	Low, NCS to Low, NCS - n (%)	1 (1.3)	1 (2.4)	2 (5.1)	4 (2.5)
		Normal to Low, NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal to Normal - n (%)	60 (75.0)	28 (68.3)	26 (66.7)	114 (71.3)
		Normal to High, NCS - n (%)	7 (8.8)	3 (7.3)	2 (5.1)	12 (7.5)
		High, NCS to Normal - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		High, NCS to High, NCS - n (%)	5 (6.3)	3 (7.3)	1 (2.6)	9 (5.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. mean corpuscular volume (fL)	Day 60	n	74	37	31	142
		Mean (SD)	92.6 (5.67)	93.1 (5.29)	91.2 (6.40)	92.4 (5.74)
		Median	93.0	93.0	92.0	93.0
		Min, Max	76, 113	78, 105	76, 104	76, 113
		Low value - n (%)	1 (1.3)	1 (2.4)	2 (5.1)	4 (2.5)
		Normal value - n (%)	60 (75.0)	29 (70.7)	25 (64.1)	114 (71.3)
		High value - n (%)	13 (16.3)	7 (17.1)	4 (10.3)	24 (15.0)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	14 (17.5)	8 (19.5)	6 (15.4)	28 (17.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. mean corpuscular volume (fL)	Change from Baseline to Day 60	n	73	37	31	141
		Mean (SD)	1.4 (2.70)	1.3 (2.25)	1.2 (2.70)	1.3 (2.58)
		Median	1.0	1.0	1.0	1.0
		Min, Max	-6, 11	-5, 6	-4, 8	-6, 11

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. mean corpuscular volume (fL)	Shift in Normality from Baseline to Day 60	Low, NCS to Low, NCS - n (%)	1 (1.3)	1 (2.4)	2 (5.1)	4 (2.5)
		Normal to Normal - n (%)	58 (72.5)	29 (70.7)	25 (64.1)	112 (70.0)
		Normal to High, NCS - n (%)	8 (10.0)	3 (7.3)	3 (7.7)	14 (8.8)
		High, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to High, NCS - n (%)	5 (6.3)	4 (9.8)	1 (2.6)	10 (6.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. mean corpuscular volume (fL)	Day 91/Discharge n Ambulatory		73	35	33	141
		Mean (SD)	91.8 (5.49)	92.7 (6.57)	90.3 (6.96)	91.7 (6.15)
		Median	92.0	93.0	91.0	92.0
		Min, Max	77, 109	76, 106	73, 102	73, 109
		Low value - n (%)	2 (2.5)	1 (2.4)	2 (5.1)	5 (3.1)
		Normal value - n (%)	64 (80.0)	28 (68.3)	26 (66.7)	118 (73.8)
		High value - n (%)	7 (8.8)	6 (14.6)	5 (12.8)	18 (11.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	9 (11.3)	7 (17.1)	7 (17.9)	23 (14.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. mean corpuscular volume (fL)	Change from Baseline to Day 91/Discharge Ambulatory	n	72	35	33	140
		Mean (SD)	0.8 (2.55)	0.8 (3.39)	0.8 (2.82)	0.8 (2.82)
		Median	1.0	0.0	0.0	1.0
		Min, Max	-4, 7	-6, 9	-4, 7	-6, 9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.17 Summary of Hematology Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Ery. mean corpuscular volume (fL)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Low, NCS to Low, NCS - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		Low, NCS to Normal - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal to Low, NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		Normal to Normal - n (%)	60 (75.0)	27 (65.9)	25 (64.1)	112 (70.0)
		Normal to High, NCS - n (%)	5 (6.3)	3 (7.3)	4 (10.3)	12 (7.5)
		High, NCS to Normal - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		High, NCS to High, NCS - n (%)	2 (2.5)	3 (7.3)	1 (2.6)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
pH	Screening	n	80	41	39	4	164
		Mean (SD)	6.30 (0.871)	6.50 (0.652)	6.22 (0.865)	6.50 (1.000)	6.34 (0.822)
		Median	6.00	6.50	6.00	6.00	6.25
		Min, Max	5.0, 8.0	5.0, 7.5	5.0, 8.0	6.0, 8.0	5.0, 8.0
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	4 (80.0)	164 (99.4)
		High value - n (%)	0	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
pH	Day 0	n	80	41	39	3	163
		Mean (SD)	5.41 (0.354)	5.39 (0.286)	5.44 (0.308)	NC	5.41 (0.324)
		Median	5.50	5.50	5.50	NC	5.50
		Min, Max	5.0, 7.0	5.0, 6.0	5.0, 6.0	NC	5.0, 7.0
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	3 (60.0)	163 (98.8)
		High value - n (%)	0	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Specific gravity	Screening	n	80	41	39	4	164
		Mean (SD)	1.0125 (0.00734)	1.0128 (0.00726)	1.0118 (0.00631)	1.0073 (0.00819)	1.0123 (0.00709)
		Median	1.0110	1.0110	1.0100	1.0050	1.0100
		Min, Max	1.000, 1.030	1.000, 1.031	1.005, 1.027	1.000, 1.019	1.000, 1.031
		Low value - n (%)	6 (7.5)	1 (2.4)	0	1 (20.0)	8 (4.8)
		Normal value - n (%)	74 (92.5)	39 (95.1)	39 (100)	3 (60.0)	155 (93.9)
		High value - n (%)	0	1 (2.4)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	6 (7.5)	2 (4.9)	0	1 (20.0)	9 (5.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Specific gravity	Day 0	n	80	41	39	3	163
		Mean (SD)	1.0162 (0.00502)	1.0159 (0.00537)	1.0169 (0.00553)	NC	1.0163 (0.00520)
		Median	1.0160	1.0150	1.0160	NC	1.0160
		Min, Max	1.007, 1.028	1.008, 1.029	1.007, 1.034	NC	1.007, 1.034
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	3 (60.0)	163 (98.8)
		High value - n (%)	0	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Bilirubin (Urine)	Screening	Negative - n (%)	80 (100)	41 (100)	38 (97.4)	3 (60.0)	162 (98.2)
		Positive - n (%)	0	0	1 (2.6)	1 (20.0)	2 (1.2)
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	38 (97.4)	3 (60.0)	162 (98.2)
		High value - n (%)	0	0	1 (2.6)	1 (20.0)	2 (1.2)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	0	1 (2.6)	1 (20.0)	2 (1.2)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Bilirubin (Urine)	Day 0	Negative - n (%)	80 (100)	41 (100)	39 (100)	3 (60.0)	163 (98.8)
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	3 (60.0)	163 (98.8)
		High value - n (%)	0	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Glucose (Urine)	Screening	Negative - n (%)	38 (47.5)	26 (63.4)	15 (38.5)	1 (20.0)	80 (48.5)
		Normal - n (%)	42 (52.5)	15 (36.6)	24 (61.5)	3 (60.0)	84 (50.9)
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	4 (80.0)	164 (99.4)
		High value - n (%)	0	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Glucose (Urine)	Screening	U.Glucose increase Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	4 (80.0)	164 (99.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Glucose (Urine)	Day 0	Normal - n (%)	80 (100)	41 (100)	39 (100)	3 (60.0)	163 (98.8)
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	3 (60.0)	163 (98.8)
		High value - n (%)	0	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Glucose (Urine)	Day 0	U.Glucose increase Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	3 (60.0)	163 (98.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Nitrite	Screening	Negative - n (%)	79 (98.8)	41 (100)	39 (100)	4 (80.0)	163 (98.8)
		Trace - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	79 (98.8)	41 (100)	39 (100)	4 (80.0)	163 (98.8)
		High value - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Nitrite	Day 0	2+ - n (%)	2 (2.5)	1 (2.4)	0	0	3 (1.8)
		Negative - n (%)	78 (97.5)	40 (97.6)	39 (100)	3 (60.0)	160 (97.0)
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	78 (97.5)	40 (97.6)	39 (100)	3 (60.0)	160 (97.0)
		High value - n (%)	2 (2.5)	1 (2.4)	0	0	3 (1.8)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	1 (2.4)	0	0	3 (1.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Erythrocytes (Urine)	Day 0	1+ - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	0	3 (1.8)
		3+ - n (%)	0	1 (2.4)	0	0	1 (0.6)
		Negative - n (%)	76 (95.0)	39 (95.1)	35 (89.7)	3 (60.0)	153 (92.7)
		Trace - n (%)	3 (3.8)	0	3 (7.7)	0	6 (3.6)
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	79 (98.8)	39 (95.1)	36 (92.3)	3 (60.0)	157 (95.2)
		High value - n (%)	1 (1.3)	2 (4.9)	3 (7.7)	0	6 (3.6)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	2 (4.9)	3 (7.7)	0	6 (3.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Protein (Urine)	Screening	Negative - n (%)	77 (96.3)	39 (95.1)	36 (92.3)	4 (80.0)	156 (94.5)
		Positive - n (%)	1 (1.3)	0	0	0	1 (0.6)
		Trace - n (%)	2 (2.5)	2 (4.9)	3 (7.7)	0	7 (4.2)
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	77 (96.3)	40 (97.6)	36 (92.3)	4 (80.0)	157 (95.2)
		High value - n (%)	3 (3.8)	1 (2.4)	3 (7.7)	0	7 (4.2)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	1 (2.4)	3 (7.7)	0	7 (4.2)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Protein (Urine)	Screening	U.Protein increase Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	4 (80.0)	164 (99.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Protein (Urine)	Day 0	1+ - n (%)	0	2 (4.9)	2 (5.1)	0	4 (2.4)
		Negative - n (%)	70 (87.5)	36 (87.8)	31 (79.5)	3 (60.0)	140 (84.8)
		Trace - n (%)	10 (12.5)	3 (7.3)	6 (15.4)	0	19 (11.5)
		Low value - n (%)	0	0	0	0	0
		Normal value - n (%)	70 (87.5)	36 (87.8)	31 (79.5)	3 (60.0)	140 (84.8)
		High value - n (%)	10 (12.5)	5 (12.2)	8 (20.5)	0	23 (13.9)
		Abnormal CS - n (%)	0	0	0	0	0
		Abnormal NCS - n (%)	10 (12.5)	5 (12.2)	8 (20.5)	0	23 (13.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Pre-Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Test Overall Safety (N=5)	Overall Safety (N=165)
Protein (Urine)	Day 0	U.Protein increase					
		Grade 0 - n (%)	80 (100)	39 (95.1)	37 (94.9)	3 (60.0)	159 (96.4)
		Grade 1 - n (%)	0	2 (4.9)	2 (5.1)	0	4 (2.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Product Test refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
pH [5-8]	Baseline	n	80	41	39	160
		Mean (SD)	5.41 (0.354)	5.39 (0.286)	5.44 (0.308)	5.41 (0.325)
		Median	5.50	5.50	5.50	5.50
		Min, Max	5.0, 7.0	5.0, 6.0	5.0, 6.0	5.0, 7.0
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	160 (100)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
pH [5-8]	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	5.41 (0.366)	5.44 (0.427)	5.41 (0.374)	5.42 (0.382)
		Median	5.50	5.50	5.50	5.50
		Min, Max	5.0, 6.5	5.0, 6.5	5.0, 6.5	5.0, 6.5
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
pH [5-8]	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	-0.01 (0.488)	0.04 (0.415)	-0.04 (0.476)	0.00 (0.465)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-1.5, 1.5	-0.5, 1.0	-0.5, 1.5	-1.5, 1.5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
pH [5-8]	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Normal - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
pH [5-8]	Day 30	n	77	39	33	149
		Mean (SD)	5.58 (0.520)	5.55 (0.377)	5.42 (0.417)	5.54 (0.466)
		Median	5.50	5.50	5.50	5.50
		Min, Max	5.0, 7.0	5.0, 6.5	5.0, 6.5	5.0, 7.0
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
pH [5-8]	Change from Baseline to Day 30	n	77	39	33	149
		Mean (SD)	0.16 (0.565)	0.14 (0.500)	-0.05 (0.490)	0.11 (0.536)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-1.5, 1.5	-0.5, 1.5	-1.0, 1.0	-1.5, 1.5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
pH [5-8]	Shift in Normality from Baseline to Day 30	Normal to Normal - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
pH [5-8]	Day 60	n	74	37	31	142
		Mean (SD)	5.55 (0.518)	5.46 (0.447)	5.52 (0.419)	5.52 (0.478)
		Median	5.50	5.50	5.50	5.50
		Min, Max	5.0, 7.0	5.0, 6.5	5.0, 6.5	5.0, 7.0
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
pH [5-8]	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	0.14 (0.532)	0.08 (0.508)	0.03 (0.386)	0.10 (0.496)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-1.0, 1.5	-0.5, 1.5	-1.0, 1.0	-1.0, 1.5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
pH [5-8]	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
pH [5-8]	Day 91/Discharge n Ambulatory		74	36	33	143
		Mean (SD)	5.50 (0.517)	5.44 (0.428)	5.45 (0.362)	5.48 (0.461)
		Median	5.50	5.50	5.50	5.50
		Min, Max	5.0, 8.0	5.0, 7.0	5.0, 6.5	5.0, 8.0
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
pH [5-8]	Change from Baseline to Day 91/Discharge Ambulatory	n	74	36	33	143
		Mean (SD)	0.09 (0.560)	0.07 (0.537)	-0.02 (0.523)	0.06 (0.544)
		Median	0.00	0.00	0.00	0.00
		Min, Max	-1.5, 2.5	-1.0, 2.0	-1.0, 1.0	-1.5, 2.5

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
pH [5-8]	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Normal - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Specific gravity	Baseline	n	80	41	39	160
		Mean (SD)	1.0162 (0.00502)	1.0159 (0.00537)	1.0169 (0.00553)	1.0163 (0.00522)
		Median	1.0160	1.0150	1.0160	1.0160
		Min, Max	1.007, 1.028	1.008, 1.029	1.007, 1.034	1.007, 1.034
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	160 (100)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Specific gravity	Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	1.0166 (0.00694)	1.0162 (0.00707)	1.0182 (0.00660)	1.0169 (0.00690)
		Median	1.0180	1.0155	1.0210	1.0180
		Min, Max	1.003, 1.028	1.005, 1.027	1.004, 1.031	1.003, 1.031
		Low value - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal value - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Specific gravity	Change from Baseline to Day 6/Discharge Confinement	n	80	40	35	155
		Mean (SD)	0.0005 (0.00794)	0.0002 (0.00705)	0.0006 (0.00761)	0.0004 (0.00760)
		Median	0.0010	0.0005	0.0010	0.0010
		Min, Max	-0.014, 0.019	-0.016, 0.017	-0.014, 0.014	-0.016, 0.019

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Specific gravity	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Low, NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Specific gravity	Day 30	n	77	39	33	149
		Mean (SD)	1.0150 (0.00615)	1.0161 (0.00652)	1.0162 (0.00632)	1.0156 (0.00627)
		Median	1.0170	1.0180	1.0170	1.0170
		Min, Max	1.004, 1.029	1.004, 1.030	1.004, 1.031	1.004, 1.031
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Specific gravity	Change from Baseline to Day 30	n	77	39	33	149
		Mean (SD)	-0.0010 (0.00688)	0.0000 (0.00796)	-0.0013 (0.00703)	-0.0008 (0.00717)
		Median	-0.0020	0.0010	0.0010	-0.0010
		Min, Max	-0.024, 0.015	-0.019, 0.015	-0.016, 0.009	-0.024, 0.015

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Specific gravity	Shift in Normality from Baseline to Day 30	Normal to Normal - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Specific gravity	Day 60	n	74	37	31	142
		Mean (SD)	1.0147 (0.00599)	1.0133 (0.00622)	1.0170 (0.00596)	1.0149 (0.00614)
		Median	1.0150	1.0120	1.0180	1.0150
		Min, Max	1.003, 1.027	1.004, 1.028	1.005, 1.029	1.003, 1.029
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Specific gravity	Change from Baseline to Day 60	n	74	37	31	142
		Mean (SD)	-0.0013 (0.00681)	-0.0026 (0.00679)	-0.0007 (0.00691)	-0.0015 (0.00681)
		Median	-0.0010	-0.0010	0.0000	-0.0010
		Min, Max	-0.019, 0.014	-0.020, 0.010	-0.014, 0.013	-0.020, 0.014

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Specific gravity	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Specific gravity	Day 91/Discharge n Ambulatory		74	36	33	143
		Mean (SD)	1.0133 (0.00585)	1.0122 (0.00591)	1.0140 (0.00640)	1.0132 (0.00599)
		Median	1.0130	1.0120	1.0150	1.0130
		Min, Max	1.003, 1.028	1.004, 1.024	1.003, 1.026	1.003, 1.028
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Specific gravity	Change from Baseline to Day 91/Discharge Ambulatory	n	74	36	33	143
		Mean (SD)	-0.0027 (0.00684)	-0.0036 (0.00741)	-0.0035 (0.00878)	-0.0031 (0.00743)
		Median	-0.0040	-0.0030	-0.0020	-0.0030
		Min, Max	-0.017, 0.012	-0.018, 0.010	-0.027, 0.011	-0.027, 0.012

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Specific gravity	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Normal - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (Urine)	Baseline	Negative - n (%)	80 (100)	41 (100)	39 (100)	160 (100)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	160 (100)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (Urine)	Day 6/Discharge Confinement	Negative - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (Urine)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Normal - n (%)	80 (100)	40 (97.6)	35 (89.7)	155 (96.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (Urine)	Day 30	Negative - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (Urine)	Shift in Normality from Baseline to Day 30	Normal to Normal - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (Urine)	Day 60	Negative - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (Urine)	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (Urine)	Day 91/Discharge Ambulatory	Negative - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Bilirubin (Urine)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Normal - n (%)	74 (92.5)	36 (87.8)	33 (84.6)	143 (89.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Baseline	Normal - n (%)	80 (100)	41 (100)	39 (100)	160 (100)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	80 (100)	41 (100)	39 (100)	160 (100)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Baseline	U.Glucose increase Grade 0 - n (%)	80 (100)	41 (100)	39 (100)	160 (100)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Day 6/Discharge Confinement	Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		Trace - n (%)	1 (1.3)	0	0	1 (0.6)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		High value - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Day 6/Discharge Confinement	U.Glucose increase				
		Grade 0 - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		Grade 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		Normal to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	U.Glucose increase				
		0 to 0 - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		0 to 1 - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Day 30	Normal - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Day 30	U.Glucose increase Grade 0 - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Shift in Normality from Baseline to Day 30	Normal to Normal - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Shift in Toxicity from Baseline to Day 30	U.Glucose increase 0 to 0 - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Day 60	Normal - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Day 60	U.Glucose increase Grade 0 - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Shift in Toxicity from Baseline to Day 60	U.Glucose increase 0 to 0 - n (%)	74 (92.5)	37 (90.2)	31 (79.5)	142 (88.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Day 91/Discharge Ambulatory	3+ - n (%)	1 (1.3)	0	0	1 (0.6)
		4+ - n (%)	0	0	1 (2.6)	1 (0.6)
		Normal - n (%)	73 (91.3)	36 (87.8)	32 (82.1)	141 (88.1)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	73 (91.3)	36 (87.8)	32 (82.1)	141 (88.1)
		High value - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Day 91/Discharge Ambulatory	U.Glucose increase				
		Grade 0 - n (%)	73 (91.3)	36 (87.8)	32 (82.1)	141 (88.1)
		Grade 3 - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Normal - n (%)	73 (91.3)	36 (87.8)	32 (82.1)	141 (88.1)
		Normal to High, NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Glucose (Urine)	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	U.Glucose increase				
		0 to 0 - n (%)	73 (91.3)	36 (87.8)	32 (82.1)	141 (88.1)
		0 to 3 - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Nitrite	Baseline	2+ - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		Negative - n (%)	78 (97.5)	40 (97.6)	39 (100)	157 (98.1)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	78 (97.5)	40 (97.6)	39 (100)	157 (98.1)
		High value - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Nitrite	Day 6/Discharge Confinement	2+ - n (%)	1 (1.3)	0	0	1 (0.6)
		Negative - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		High value - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Nitrite	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Normal - n (%)	78 (97.5)	40 (97.6)	35 (89.7)	153 (95.6)
		High, NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		High, NCS to High, NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Nitrite	Day 30	Negative - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	77 (96.3)	39 (95.1)	33 (84.6)	149 (93.1)
		High value - n (%)	0	0	0	0
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Nitrite	Shift in Normality from Baseline to Day 30	Normal to Normal - n (%)	75 (93.8)	39 (95.1)	33 (84.6)	147 (91.9)
		High, NCS to Normal - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Nitrite	Day 60	2+ - n (%)	0	1 (2.4)	0	1 (0.6)
		Negative - n (%)	74 (92.5)	36 (87.8)	31 (79.5)	141 (88.1)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	36 (87.8)	31 (79.5)	141 (88.1)
		High value - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	1 (2.4)	0	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Nitrite	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	72 (90.0)	36 (87.8)	31 (79.5)	139 (86.9)
		Normal to High, NCS - n (%)	0	1 (2.4)	0	1 (0.6)
		High, NCS to Normal - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

Appendix 15.3.6.8

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Nitrite	Day 91/Discharge 2+ - n (%) Ambulatory		0	0	1 (2.6)	1 (0.6)
		Negative - n (%)	74 (92.5)	36 (87.8)	32 (82.1)	142 (88.8)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	74 (92.5)	36 (87.8)	32 (82.1)	142 (88.8)
		High value - n (%)	0	0	1 (2.6)	1 (0.6)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Nitrite	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Normal - n (%)	72 (90.0)	36 (87.8)	32 (82.1)	140 (87.5)
		Normal to High, NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		High, NCS to Normal - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (Urine)	Baseline	1+ - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		3+ - n (%)	0	1 (2.4)	0	1 (0.6)
		Negative - n (%)	76 (95.0)	39 (95.1)	35 (89.7)	150 (93.8)
		Trace - n (%)	3 (3.8)	0	3 (7.7)	6 (3.8)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	79 (98.8)	39 (95.1)	36 (92.3)	154 (96.3)
		High value - n (%)	1 (1.3)	2 (4.9)	3 (7.7)	6 (3.8)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	1 (1.3)	2 (4.9)	3 (7.7)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (Urine)	Day 6/Discharge Confinement	1+ - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		Negative - n (%)	77 (96.3)	38 (92.7)	32 (82.1)	147 (91.9)
		Trace - n (%)	0	2 (4.9)	2 (5.1)	4 (2.5)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	77 (96.3)	40 (97.6)	34 (87.2)	151 (94.4)
		High value - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (Urine)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Normal - n (%)	76 (95.0)	38 (92.7)	31 (79.5)	145 (90.6)
		Normal to High, NCS - n (%)	3 (3.8)	0	1 (2.6)	4 (2.5)
		High, NCS to Normal - n (%)	1 (1.3)	2 (4.9)	3 (7.7)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (Urine)	Day 30	1+ - n (%)	1 (1.3)	1 (2.4)	1 (2.6)	3 (1.9)
		2+ - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
		3+ - n (%)	1 (1.3)	0	0	1 (0.6)
		Negative - n (%)	71 (88.8)	37 (90.2)	30 (76.9)	138 (86.3)
		Trace - n (%)	4 (5.0)	0	1 (2.6)	5 (3.1)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	75 (93.8)	37 (90.2)	31 (79.5)	143 (89.4)
		High value - n (%)	2 (2.5)	2 (4.9)	2 (5.1)	6 (3.8)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	2 (4.9)	2 (5.1)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (Urine)	Shift in Normality from Baseline to Day 30	Normal to Normal - n (%)	75 (93.8)	36 (87.8)	30 (76.9)	141 (88.1)
		Normal to High, NCS - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		High, NCS to Normal - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
		High, NCS to High, NCS - n (%)	1 (1.3)	1 (2.4)	2 (5.1)	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (Urine)	Day 60	1+ - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		2+ - n (%)	1 (1.3)	0	3 (7.7)	4 (2.5)
		Negative - n (%)	71 (88.8)	37 (90.2)	27 (69.2)	135 (84.4)
		Trace - n (%)	1 (1.3)	0	0	1 (0.6)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	72 (90.0)	37 (90.2)	27 (69.2)	136 (85.0)
		High value - n (%)	2 (2.5)	0	4 (10.3)	6 (3.8)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	2 (2.5)	0	4 (10.3)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (Urine)	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	71 (88.8)	37 (90.2)	26 (66.7)	134 (83.8)
		Normal to High, NCS - n (%)	2 (2.5)	0	2 (5.1)	4 (2.5)
		High, NCS to Normal - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		High, NCS to High, NCS - n (%)	0	0	2 (5.1)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (Urine)	Day 91/Discharge Ambulatory	1+ - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		2+ - n (%)	2 (2.5)	0	1 (2.6)	3 (1.9)
		Negative - n (%)	70 (87.5)	36 (87.8)	28 (71.8)	134 (83.8)
		Trace - n (%)	1 (1.3)	0	3 (7.7)	4 (2.5)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	71 (88.8)	36 (87.8)	29 (74.4)	136 (85.0)
		High value - n (%)	3 (3.8)	0	4 (10.3)	7 (4.4)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	3 (3.8)	0	4 (10.3)	7 (4.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Erythrocytes (Urine)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Normal - n (%)	70 (87.5)	36 (87.8)	28 (71.8)	134 (83.8)
		Normal to High, NCS - n (%)	3 (3.8)	0	2 (5.1)	5 (3.1)
		High, NCS to Normal - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		High, NCS to High, NCS - n (%)	0	0	2 (5.1)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Baseline	1+ - n (%)	0	2 (4.9)	2 (5.1)	4 (2.5)
		Negative - n (%)	70 (87.5)	36 (87.8)	31 (79.5)	137 (85.6)
		Trace - n (%)	10 (12.5)	3 (7.3)	6 (15.4)	19 (11.9)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	70 (87.5)	36 (87.8)	31 (79.5)	137 (85.6)
		High value - n (%)	10 (12.5)	5 (12.2)	8 (20.5)	23 (14.4)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	10 (12.5)	5 (12.2)	8 (20.5)	23 (14.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Baseline	U.Protein increase				
		Grade 0 - n (%)	80 (100)	39 (95.1)	37 (94.9)	156 (97.5)
		Grade 1 - n (%)	0	2 (4.9)	2 (5.1)	4 (2.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Day 6/Discharge Confinement	1+ - n (%)	4 (5.0)	2 (4.9)	4 (10.3)	10 (6.3)
		2+ - n (%)	0	0	1 (2.6)	1 (0.6)
		Negative - n (%)	50 (62.5)	27 (65.9)	18 (46.2)	95 (59.4)
		Trace - n (%)	26 (32.5)	11 (26.8)	12 (30.8)	49 (30.6)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	50 (62.5)	27 (65.9)	18 (46.2)	95 (59.4)
		High value - n (%)	30 (37.5)	13 (31.7)	17 (43.6)	60 (37.5)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	29 (36.3)	13 (31.7)	17 (43.6)	59 (36.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Day 6/Discharge Confinement	U.Protein increase				
		Grade 0 - n (%)	76 (95.0)	38 (92.7)	30 (76.9)	144 (90.0)
		Grade 1 - n (%)	4 (5.0)	2 (4.9)	4 (10.3)	10 (6.3)
		Grade 2 - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Shift in Normality from Baseline to Day 6/Discharge Confinement	Normal to Normal - n (%)	47 (58.8)	24 (58.5)	16 (41.0)	87 (54.4)
		Normal to High - n (%)	1 (1.3)	0	0	1 (0.6)
		Normal to High, NCS - n (%)	22 (27.5)	11 (26.8)	11 (28.2)	44 (27.5)
		High, NCS to Normal - n (%)	3 (3.8)	3 (7.3)	2 (5.1)	8 (5.0)
		High, NCS to High, NCS - n (%)	7 (8.8)	2 (4.9)	6 (15.4)	15 (9.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Shift in Toxicity from Baseline to Day 6/Discharge Confinement	U.Protein increase				
		0 to 0 - n (%)	76 (95.0)	36 (87.8)	30 (76.9)	142 (88.8)
		0 to 1 - n (%)	4 (5.0)	2 (4.9)	3 (7.7)	9 (5.6)
		1 to 0 - n (%)	0	2 (4.9)	0	2 (1.3)
		1 to 1 - n (%)	0	0	1 (2.6)	1 (0.6)
		1 to 2 - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Day 30	1+ - n (%)	0	1 (2.4)	0	1 (0.6)
		2+ - n (%)	0	0	2 (5.1)	2 (1.3)
		Negative - n (%)	63 (78.8)	30 (73.2)	27 (69.2)	120 (75.0)
		Trace - n (%)	14 (17.5)	8 (19.5)	4 (10.3)	26 (16.3)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	63 (78.8)	30 (73.2)	27 (69.2)	120 (75.0)
		High value - n (%)	14 (17.5)	9 (22.0)	6 (15.4)	29 (18.1)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	14 (17.5)	9 (22.0)	6 (15.4)	29 (18.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Day 30	U.Protein increase				
		Grade 0 - n (%)	77 (96.3)	38 (92.7)	31 (79.5)	146 (91.3)
		Grade 1 - n (%)	0	1 (2.4)	0	1 (0.6)
		Grade 2 - n (%)	0	0	2 (5.1)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Shift in Normality from Baseline to Day 30	Normal to Normal - n (%)	58 (72.5)	26 (63.4)	21 (53.8)	105 (65.6)
		Normal to High, NCS - n (%)	10 (12.5)	8 (19.5)	4 (10.3)	22 (13.8)
		High, NCS to Normal - n (%)	5 (6.3)	4 (9.8)	6 (15.4)	15 (9.4)
		High, NCS to High, NCS - n (%)	4 (5.0)	1 (2.4)	2 (5.1)	7 (4.4)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Shift in Toxicity from Baseline to Day 30	U.Protein increase				
		0 to 0 - n (%)	77 (96.3)	36 (87.8)	31 (79.5)	144 (90.0)
		0 to 1 - n (%)	0	1 (2.4)	0	1 (0.6)
		1 to 0 - n (%)	0	2 (4.9)	0	2 (1.3)
		1 to 2 - n (%)	0	0	2 (5.1)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Day 60	1+ - n (%)	1 (1.3)	1 (2.4)	4 (10.3)	6 (3.8)
		Negative - n (%)	61 (76.3)	31 (75.6)	22 (56.4)	114 (71.3)
		Trace - n (%)	12 (15.0)	5 (12.2)	5 (12.8)	22 (13.8)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	61 (76.3)	31 (75.6)	22 (56.4)	114 (71.3)
		High value - n (%)	13 (16.3)	6 (14.6)	9 (23.1)	28 (17.5)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	13 (16.3)	6 (14.6)	9 (23.1)	28 (17.5)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Day 60	U.Protein increase				
		Grade 0 - n (%)	73 (91.3)	36 (87.8)	27 (69.2)	136 (85.0)
		Grade 1 - n (%)	1 (1.3)	1 (2.4)	4 (10.3)	6 (3.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Shift in Normality from Baseline to Day 60	Normal to Normal - n (%)	57 (71.3)	28 (68.3)	19 (48.7)	104 (65.0)
		Normal to High, NCS - n (%)	8 (10.0)	5 (12.2)	4 (10.3)	17 (10.6)
		High, NCS to Normal - n (%)	4 (5.0)	3 (7.3)	3 (7.7)	10 (6.3)
		High, NCS to High, NCS - n (%)	5 (6.3)	1 (2.4)	5 (12.8)	11 (6.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Shift in Toxicity from Baseline to Day 60	U.Protein increase				
		0 to 0 - n (%)	73 (91.3)	35 (85.4)	25 (64.1)	133 (83.1)
		0 to 1 - n (%)	1 (1.3)	1 (2.4)	4 (10.3)	6 (3.8)
		1 to 0 - n (%)	0	1 (2.4)	2 (5.1)	3 (1.9)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Day 91/Discharge Ambulatory	1+ - n (%)	3 (3.8)	1 (2.4)	1 (2.6)	5 (3.1)
		Negative - n (%)	66 (82.5)	33 (80.5)	30 (76.9)	129 (80.6)
		Trace - n (%)	5 (6.3)	2 (4.9)	2 (5.1)	9 (5.6)
		Low value - n (%)	0	0	0	0
		Normal value - n (%)	66 (82.5)	33 (80.5)	30 (76.9)	129 (80.6)
		High value - n (%)	8 (10.0)	3 (7.3)	3 (7.7)	14 (8.8)
		Abnormal CS - n (%)	0	0	0	0
		Abnormal NCS - n (%)	8 (10.0)	3 (7.3)	3 (7.7)	14 (8.8)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Day 91/Discharge Ambulatory	U.Protein increase				
		Grade 0 - n (%)	71 (88.8)	35 (85.4)	32 (82.1)	138 (86.3)
		Grade 1 - n (%)	3 (3.8)	1 (2.4)	1 (2.6)	5 (3.1)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Shift in Normality from Baseline to Day 91/Discharge Ambulatory	Normal to Normal - n (%)	58 (72.5)	29 (70.7)	23 (59.0)	110 (68.8)
		Normal to High, NCS - n (%)	7 (8.8)	3 (7.3)	2 (5.1)	12 (7.5)
		High, NCS to Normal - n (%)	8 (10.0)	4 (9.8)	7 (17.9)	19 (11.9)
		High, NCS to High, NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

**Table 15.2.6.18 Summary of Urinalysis Parameters - Safety Population****Safety Time Period: Randomized Period**

Param (units) [Reference range]	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
Protein (Urine)	Shift in Toxicity from Baseline to Day 91/Discharge Ambulatory	U.Protein increase				
		0 to 0 - n (%)	71 (88.8)	34 (82.9)	31 (79.5)	136 (85.0)
		0 to 1 - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		1 to 0 - n (%)	0	1 (2.4)	1 (2.6)	2 (1.3)
		1 to 1 - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: The Overall Safety refers to the safety population post-randomization.

Note: NCS = Not Clinically Significant, CS=Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

Note: Normality ranges for this parameter are provided in Appendix.

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**Table 15.2.6.19.1 Summary of Concomitant Medication by Anatomical Therapeutic Classes (ATC) 1 and 2 - Safety Population****Safety Time Period: Pre-Randomization**

ATC1 ATC2	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any Medication	14 (17.5)	17	6 (14.6)	10	8 (20.5)	11	1 (20.0)	35	29 (17.6)	73
Genito Urinary System And Sex Hormones	6 (7.5)	6	1 (2.4)	1	3 (7.7)	3	0	0	10 (6.1)	10
Sex Hormones And Modulators Of The Genital System	5 (6.3)	5	1 (2.4)	1	2 (5.1)	2			8 (4.9)	8
Other Gynecologicals	1 (1.3)	1	0	0	0	0			1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.1 Summary of Concomitant Medication by Anatomical Therapeutic Classes (ATC) 1 and 2 - Safety Population****Safety Time Period: Pre-Randomization**

ATC1 ATC2	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Urologicals	0	0	0	0	1 (2.6)	1			1 (0.6)	1
Alimentary Tract And Metabolism	5 (6.3)	7	1 (2.4)	3	2 (5.1)	2	1 (20.0)	17	9 (5.5)	29
Vitamins	4 (5.0)	6	1 (2.4)	1	1 (2.6)	1	0	0	6 (3.6)	8
Drugs For Acid Related Disorders	0	0	0	0	1 (2.6)	1	1 (20.0)	2	2 (1.2)	3
Mineral Supplements	1 (1.3)	1	0	0	0	0	1 (20.0)	3	2 (1.2)	4

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.1 Summary of Concomitant Medication by Anatomical Therapeutic Classes (ATC) 1 and 2 - Safety Population****Safety Time Period: Pre-Randomization**

ATC1 ATC2	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Antidiarrheals, Intestinal Antiinflammatory/Antiinfective Agents	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1
Antiemetics And Antinauseants	0	0	0	0	0	0	1 (20.0)	3	1 (0.6)	3
Drugs For Constipation	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Drugs For Functional Gastrointestinal Disorders	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Drugs Used In Diabetes	0	0	0	0	0	0	1 (20.0)	7	1 (0.6)	7

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.1 Summary of Concomitant Medication by Anatomical Therapeutic Classes (ATC) 1 and 2 - Safety Population****Safety Time Period: Pre-Randomization**

ATC1 ATC2	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Other Alimentary Tract And Metabolism Products	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1
Nervous System	0	0	2 (4.9)	2	3 (7.7)	3	1 (20.0)	6	6 (3.6)	11
Analgesics			2 (4.9)	2	2 (5.1)	2	1 (20.0)	4	5 (3.0)	8
Other Nervous System Drugs			0	0	1 (2.6)	1	0	0	1 (0.6)	1
Psycholeptics			0	0	0	0	1 (20.0)	2	1 (0.6)	2

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.1 Summary of Concomitant Medication by Anatomical Therapeutic Classes (ATC) 1 and 2 - Safety Population****Safety Time Period: Pre-Randomization**

	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
ATC1										
ATC2										
Respiratory System	1 (1.3)	1	2 (4.9)	2	0	0	1 (20.0)	2	4 (2.4)	5
Nasal Preparations	1 (1.3)	1	1 (2.4)	1			1 (20.0)	1	3 (1.8)	3
Antihistamines For Systemic Use	0	0	1 (2.4)	1			1 (20.0)	1	2 (1.2)	2
Antiinfectives For Systemic Use	1 (1.3)	1	0	0	2 (5.1)	2	1 (20.0)	1	4 (2.4)	4
Antibacterials For Systemic Use	1 (1.3)	1			1 (2.6)	1	1 (20.0)	1	3 (1.8)	3

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.1 Summary of Concomitant Medication by Anatomical Therapeutic Classes (ATC) 1 and 2 - Safety Population****Safety Time Period: Pre-Randomization**

	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
ATC1										
ATC2										
Antivirals For Systemic Use	0	0			1 (2.6)	1	0	0	1 (0.6)	1
Various	1 (1.3)	1	0	0	0	0	1 (20.0)	1	2 (1.2)	2
General Nutrients	1 (1.3)	1					1 (20.0)	1	2 (1.2)	2
Blood And Blood Forming Organs	0	0	0	0	0	0	1 (20.0)	8	1 (0.6)	8
Antithrombotic Agents							1 (20.0)	1	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.1 Summary of Concomitant Medication by Anatomical Therapeutic Classes (ATC) 1 and 2 - Safety Population****Safety Time Period: Pre-Randomization**

ATC1 ATC2	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Blood Substitutes And Perfusion Solutions							1 (20.0)	7	1 (0.6)	7
Cardiovascular System	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1
Lipid Modifying Agents			1 (2.4)	1					1 (0.6)	1
Dermatologicals	0	0	0	0	1 (2.6)	1	0	0	1 (0.6)	1
Antibiotics And Chemotherapeutics For Dermatological Use					1 (2.6)	1			1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.1 Summary of Concomitant Medication by Anatomical Therapeutic Classes (ATC) 1 and 2 - Safety Population****Safety Time Period: Pre-Randomization**

ATC1 ATC2	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Sensory Organs	1 (1.3)	1	0	0	0	0	0	0	1 (0.6)	1
Ophthalmologicals	1 (1.3)	1							1 (0.6)	1
Systemic Hormonal Preparations, Excl. Sex Hormones And Insulins	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1
Thyroid Therapy			1 (2.4)	1					1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.1 Summary of Concomitant Medication by Anatomical Therapeutic Classes (ATC) 1 and 2 - Safety Population****Safety Time Period: Randomization**

ATC1 ATC2	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any Medication	14 (17.5)	18	9 (22.0)	10	15 (38.5)	24	38 (23.8)	52
Nervous System	5 (6.3)	6	2 (4.9)	2	14 (35.9)	17	21 (13.1)	25
Analgesics	5 (6.3)	6	2 (4.9)	2	5 (12.8)	5	12 (7.5)	13
Other Nervous System Drugs	0	0	0	0	10 (25.6)	12	10 (6.3)	12

Note: The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.1 Summary of Concomitant Medication by Anatomical Therapeutic Classes (ATC) 1 and 2 - Safety Population****Safety Time Period: Randomization**

ATC1 ATC2	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Respiratory System	4 (5.0)	4	4 (9.8)	4	1 (2.6)	1	9 (5.6)	9
Nasal Preparations	2 (2.5)	2	2 (4.9)	2	0	0	4 (2.5)	4
Cough And Cold Preparations	2 (2.5)	2	1 (2.4)	1	0	0	3 (1.9)	3
Antihistamines For Systemic Use	0	0	1 (2.4)	1	1 (2.6)	1	2 (1.3)	2
Alimentary Tract And Metabolism	3 (3.8)	3	0	0	1 (2.6)	1	4 (2.5)	4

Note: The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.1 Summary of Concomitant Medication by Anatomical Therapeutic Classes (ATC) 1 and 2 - Safety Population****Safety Time Period: Randomization**

ATC1 ATC2	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Drugs For Acid Related Disorders	2 (2.5)	2			0	0	2 (1.3)	2
Stomatological Preparations	1 (1.3)	1			1 (2.6)	1	2 (1.3)	2
Dermatologicals	1 (1.3)	1	2 (4.9)	2	1 (2.6)	1	4 (2.5)	4
Antiseptics And Disinfectants	1 (1.3)	1	1 (2.4)	1	0	0	2 (1.3)	2
Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	0	0	1 (2.4)	1	0	0	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.1 Summary of Concomitant Medication by Anatomical Therapeutic Classes (ATC) 1 and 2 - Safety Population****Safety Time Period: Randomization**

ATC1 ATC2	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Emollients And Protectives	0	0	0	0	1 (2.6)	1	1 (0.6)	1
Musculo-Skeletal System	0	0	1 (2.4)	1	2 (5.1)	3	3 (1.9)	4
Antiinflammatory And Antirheumatic Products			1 (2.4)	1	1 (2.6)	2	2 (1.3)	3
Muscle Relaxants			0	0	1 (2.6)	1	1 (0.6)	1
Antifectives For Systemic Use	2 (2.5)	2	1 (2.4)	1	0	0	3 (1.9)	3

Note: The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.1 Summary of Concomitant Medication by Anatomical Therapeutic Classes (ATC) 1 and 2 - Safety Population****Safety Time Period: Randomization**

	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
ATC1 ATC2	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Antibacterials For Systemic Use	2 (2.5)	2	0	0			2 (1.3)	2
Vaccines	0	0	1 (2.4)	1			1 (0.6)	1
Genito Urinary System And Sex Hormones	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Urologicals	1 (1.3)	1					1 (0.6)	1
Sensory Organs	0	0	0	0	1 (2.6)	1	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.1 Summary of Concomitant Medication by Anatomical Therapeutic Classes (ATC) 1 and 2 - Safety Population****Safety Time Period: Randomization**

ATC1 ATC2	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Otologicals					1 (2.6)	1	1 (0.6)	1
Various	1 (1.3)	1	0	0	0	0	1 (0.6)	1
All Other Therapeutic Products	1 (1.3)	1					1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.2 Summary of Concomitant Medication by Preferred Drug Name - Safety Population****Safety Time Period: Pre-Randomization**

Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any Medication	14 (17.5)	17	6 (14.6)	10	8 (20.5)	11	1 (20.0)	35	29 (17.6)	73
Paracetamol	0	0	2 (4.9)	2	1 (2.6)	1	1 (20.0)	1	4 (2.4)	4
Ascorbic Acid	2 (2.5)	2	0	0	0	0	0	0	2 (1.2)	2
Contac	1 (1.3)	1	1 (2.4)	1	0	0	0	0	2 (1.2)	2
Levonorgestrel	2 (2.5)	2	0	0	0	0	0	0	2 (1.2)	2
Minerals Nos W/Vitamins Nos	2 (2.5)	2	0	0	0	0	0	0	2 (1.2)	2
Multivitamins, Plain	1 (1.3)	1	1 (2.4)	1	0	0	0	0	2 (1.2)	2
Pantoprazole	0	0	0	0	1 (2.6)	1	1 (20.0)	1	2 (1.2)	2
Aciclovir	0	0	0	0	1 (2.6)	2	0	0	1 (0.6)	2

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.2 Summary of Concomitant Medication by Preferred Drug Name - Safety Population****Safety Time Period: Pre-Randomization**

Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Prochlorperazine	0	0	0	0	0	0	1 (20.0)	2	1 (0.6)	2
Azithromycin	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Biotin	1 (1.3)	1	0	0	0	0	0	0	1 (0.6)	1
Calcium Carbonate	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Centrum	0	0	0	0	1 (2.6)	1	0	0	1 (0.6)	1
Cetirizine Hydrochloride	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1
Cilest	1 (1.3)	1	0	0	0	0	0	0	1 (0.6)	1
Clindamycin	1 (1.3)	1	0	0	0	0	0	0	1 (0.6)	1
Dextrose And Sodium Chloride Injection	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Docusate Sodium	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.2 Summary of Concomitant Medication by Preferred Drug Name - Safety Population****Safety Time Period: Pre-Randomization**

Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
El-4	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Electrolyte Solutions	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Enoxaparin Sodium	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Estradiol	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1
Estrogens Conjugated	1 (1.3)	1	0	0	0	0	0	0	1 (0.6)	1
Etonogestrel	1 (1.3)	1	0	0	0	0	0	0	1 (0.6)	1
Fibre, Dietary	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1
Finasteride	0	0	0	0	1 (2.6)	1	0	0	1 (0.6)	1
Fish Oil	1 (1.3)	1	0	0	0	0	0	0	1 (0.6)	1
Fluticasone Propionate	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.2 Summary of Concomitant Medication by Preferred Drug Name - Safety Population****Safety Time Period: Pre-Randomization**

Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Glucose	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Human Mixtard	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Hydrocodone	0	0	0	0	1 (2.6)	1	0	0	1 (0.6)	1
Insulin	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Insulin Aspart	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Insulin Detemir	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Insulin Human	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Intrauterine Contraceptive Device	1 (1.3)	1	0	0	0	0	0	0	1 (0.6)	1
Lactobacillus Acidophilus	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1
Levothyroxine	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.2 Summary of Concomitant Medication by Preferred Drug Name - Safety Population****Safety Time Period: Pre-Randomization**

Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Loratadine	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Magnesium Oxide	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Magnesol	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Medroxyprogesterone	0	0	0	0	1 (2.6)	1	0	0	1 (0.6)	1
Medroxyprogesterone Acetate	0	0	0	0	1 (2.6)	1	0	0	1 (0.6)	1
Metformin	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Metoclopramide Hydrochloride	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Minocycline	0	0	0	0	1 (2.6)	1	0	0	1 (0.6)	1
Morphine Sulfate	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Nicotine	0	0	0	0	1 (2.6)	1	0	0	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.2 Summary of Concomitant Medication by Preferred Drug Name - Safety Population****Safety Time Period: Pre-Randomization**

Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Novolog Mix	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Ondansetron Hydrochloride	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Osmotan	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Other Mineral Products	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Oxycocet	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Potassium Chloride	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Procet	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Simeco	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Simvastatin	0	0	1 (2.4)	1	0	0	0	0	1 (0.6)	1
Sodium Chloride	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.2 Summary of Concomitant Medication by Preferred Drug Name - Safety Population****Safety Time Period: Pre-Randomization**

Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Temazepam	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1
Visine Advanced Relief	1 (1.3)	1	0	0	0	0	0	0	1 (0.6)	1
Vitamin D Nos	1 (1.3)	1	0	0	0	0	0	0	1 (0.6)	1
Zolpidem Tartrate	0	0	0	0	0	0	1 (20.0)	1	1 (0.6)	1

Note: "Product Test" refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.2 Summary of Concomitant Medication by Preferred Drug Name - Safety Population****Safety Time Period: Randomization**

Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any Medication	14 (17.5)	18	9 (22.0)	10	15 (38.5)	24	38 (23.8)	52
Paracetamol	5 (6.3)	5	2 (4.9)	2	5 (12.8)	5	12 (7.5)	12
Nicotine	0	0	0	0	9 (23.1)	11	9 (5.6)	11
Benadryl Cold And Flu	1 (1.3)	1	1 (2.4)	1	0	0	2 (1.3)	2
Pseudoephedrine	1 (1.3)	1	1 (2.4)	1	0	0	2 (1.3)	2
Simeco	2 (2.5)	2	0	0	0	0	2 (1.3)	2
Triclosan	1 (1.3)	1	1 (2.4)	1	0	0	2 (1.3)	2
Ibuprofen	0	0	0	0	1 (2.6)	2	1 (0.6)	2
Acetylsalicylic Acid	1 (1.3)	1	0	0	0	0	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.2 Summary of Concomitant Medication by Preferred Drug Name - Safety Population****Safety Time Period: Randomization**

Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
All Other Therapeutic Products	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Benzocaine	0	0	0	0	1 (2.6)	1	1 (0.6)	1
Carisoprodol	0	0	0	0	1 (2.6)	1	1 (0.6)	1
Ciprofloxacin	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Co-Advil	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Diphenhydramine Hydrochloride	0	0	0	0	1 (2.6)	1	1 (0.6)	1
Hydrocodone	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Lidocaine Hydrochloride	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Loratadine	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Loratadine W/Pseudoephedrine	0	0	1 (2.4)	1	0	0	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.19.2 Summary of Concomitant Medication by Preferred Drug Name - Safety Population****Safety Time Period: Randomization**

Preferred Term	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Nicotine Polacrilex	0	0	0	0	1 (2.6)	1	1 (0.6)	1
Otosporin	0	0	0	0	1 (2.6)	1	1 (0.6)	1
Penicillin Nos	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Phenazopyridine	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Phenylephrine Hydrochloride	1 (1.3)	1	0	0	0	0	1 (0.6)	1
Salicylic Acid	0	0	0	0	1 (2.6)	1	1 (0.6)	1
Tetanus Vaccine	0	0	1 (2.4)	1	0	0	1 (0.6)	1
Vicks Vaporub	1 (1.3)	1	0	0	0	0	1 (0.6)	1

Note: The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Systolic Blood Pressure Baseline (mmHg)	Day 1	n	79		41		39		159	
		Mean	118.8		119.1		113.5		117.6	
		(SD)	(9.60)		(9.82)		(9.86)		(9.94)	
		Median	119.0		118.0		113.0		116.0	
		Min, Max	100, 152		90, 139		96, 135		90, 152	
		n	78	78	40	40	29	29	147	147
		Mean	115.3	-3.7	114.8	-4.1	111.1	-4.8	114.4	-4.0
		(SD)	(9.14)	(8.40)	(8.12)	(8.26)	(10.02)	(7.92)	(9.14)	(8.23)
		Median	114.0	-3.0	115.5	-4.0	109.0	-4.0	114.0	-3.0
		Min, Max	97, 137	-29, 16	91, 138	-21, 14	87, 132	-30, 9	87, 138	-30, 16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Systolic Blood Pressure Day 2 (mmHg)		n	79	79	40	40	34	34	153	153
		Mean	114.4	-4.4	113.4	-5.5	110.9	-2.6	113.3	-4.3
		(SD)	(9.64)	(7.62)	(8.30)	(8.70)	(9.09)	(8.40)	(9.23)	(8.10)
		Median	114.0	-6.0	114.0	-7.0	110.0	-3.0	113.0	-6.0
	Day 3	Min, Max	97, 139	-20, 14	94, 131	-20, 18	96, 131	-17, 16	94, 139	-20, 18
		n	79	79	40	40	34	34	153	153
		Mean	114.6	-4.2	117.0	-1.9	110.3	-3.1	114.3	-3.4
		(SD)	(8.49)	(8.39)	(9.09)	(7.71)	(9.32)	(8.37)	(9.08)	(8.22)
		Median	114.0	-5.0	117.5	-2.0	110.0	-5.0	114.0	-4.0
		Min, Max	97, 135	-32, 16	97, 133	-18, 13	90, 130	-20, 16	90, 135	-32, 16

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Systolic Blood Pressure Day 4 (mmHg)		n	79	79	40	40	34	34	153	153
		Mean	113.8	-5.0	116.4	-2.5	109.3	-4.1	113.5	-4.2
		(SD)	(8.20)	(8.11)	(7.92)	(7.90)	(9.63)	(9.46)	(8.77)	(8.39)
		Median	113.0	-5.0	116.0	-3.0	107.0	-5.5	113.0	-4.0
	Day 5	Min, Max	96, 139	-37, 10	95, 137	-24, 13	93, 127	-21, 14	93, 139	-37, 14
		n	79	79	40	40	34	34	153	153
		Mean	116.2	-2.6	118.6	-0.3	112.8	-0.6	116.1	-1.5
		(SD)	(10.11)	(8.48)	(9.94)	(8.82)	(8.31)	(8.64)	(9.85)	(8.61)
		Median	116.0	-3.0	117.5	0.0	112.5	0.5	115.0	-2.0
		Min, Max	94, 150	-22, 26	97, 147	-23, 18	93, 126	-25, 16	93, 150	-25, 26

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Systolic Blood Pressure Day 30 (mmHg)	Day 6/Discharge Confinement	n	79	79	41	40	39	37	159	156
		Mean	117.7	-1.1	117.1	-2.1	112.6	-0.9	116.3	-1.3
		(SD)	(11.14)	(9.63)	(11.24)	(8.70)	(10.25)	(10.86)	(11.09)	(9.66)
		Median	118.0	-1.0	115.0	-2.0	111.0	-2.0	115.0	-1.0
		Min, Max	92, 148	-30, 25	96, 155	-22, 16	92, 148	-18, 33	92, 155	-30, 33
		n	79	79	41	40	39	37	159	156
		Mean	117.0	-1.8	118.9	-0.2	113.2	-0.4	116.6	-1.0
		(SD)	(9.95)	(9.15)	(10.80)	(9.62)	(8.70)	(9.50)	(10.05)	(9.32)
		Median	117.0	-1.0	118.0	-2.0	112.0	-2.0	116.0	-2.0
		Min, Max	91, 151	-39, 14	96, 143	-25, 26	95, 135	-17, 19	91, 151	-39, 26

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Systolic Blood Pressure Day 60 (mmHg)		n	79	79	41	40	39	37	159	156
		Mean	116.8	-2.0	115.9	-3.4	113.5	0.0	115.7	-1.9
		(SD)	(11.82)	(10.98)	(11.55)	(9.98)	(8.23)	(9.09)	(10.99)	(10.31)
		Median	116.0	-2.0	114.0	-1.5	113.0	0.0	114.0	-1.0
	Day 91/Discharge Ambulatory	Min, Max	85, 152	-46, 28	91, 140	-29, 21	99, 134	-16, 21	85, 152	-46, 28
		n	79	79	41	40	39	37	159	156
		Mean	117.6	-1.2	117.6	-1.6	115.3	1.9	117.0	-0.6
		(SD)	(10.92)	(8.14)	(9.82)	(8.19)	(9.56)	(13.14)	(10.31)	(9.60)
		Median	117.0	-1.0	116.0	-1.5	114.0	-1.0	116.0	-1.0
		Min, Max	87, 144	-28, 16	97, 136	-25, 17	95, 139	-27, 38	87, 144	-28, 38

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Diastolic Blood Pressure (mmHg)	Baseline	n	79		41		39		159	
		Mean	71.9		72.8		69.9		71.6	
		(SD)	(8.04)		(7.89)		(8.39)		(8.10)	
		Median	72.0		71.0		71.0		72.0	
	Day 1	Min, Max	52, 90		54, 90		53, 85		52, 90	
		n	78	78	40	40	29	29	147	147
		Mean	68.5	-3.6	68.7	-4.2	66.9	-4.6	68.3	-3.9
		(SD)	(8.14)	(7.01)	(7.48)	(7.05)	(8.17)	(7.15)	(7.95)	(7.01)
		Median	67.5	-3.0	69.0	-3.0	67.0	-5.0	68.0	-4.0
		Min, Max	40, 89	-23, 11	55, 85	-25, 7	53, 89	-22, 8	40, 89	-25, 11

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Diastolic Blood Pressure (mmHg)	Day 2	n	79	79	40	40	34	34	153	153
		Mean	68.5	-3.4	69.0	-3.9	65.5	-4.3	68.0	-3.7
		(SD)	(8.14)	(6.93)	(8.33)	(8.30)	(9.06)	(8.34)	(8.45)	(7.59)
		Median	68.0	-3.0	67.0	-2.5	64.5	-4.5	67.0	-4.0
	Day 3	Min, Max	53, 91	-22, 14	52, 88	-23, 26	47, 90	-23, 13	47, 91	-23, 26
		n	79	79	40	40	34	34	153	153
		Mean	69.2	-2.7	70.8	-2.1	66.3	-3.5	68.9	-2.7
		(SD)	(7.09)	(6.84)	(7.99)	(6.10)	(9.10)	(6.99)	(7.91)	(6.66)
		Median	68.0	-2.0	71.0	-1.0	65.5	-4.0	68.0	-2.0
		Min, Max	53, 91	-20, 12	52, 90	-18, 8	52, 90	-24, 8	52, 91	-24, 12

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Diastolic Blood Pressure (mmHg)	Day 4	n	79	79	40	40	34	34	153	153
		Mean	67.6	-4.3	69.4	-3.5	64.0	-5.8	67.2	-4.4
		(SD)	(6.34)	(6.64)	(8.16)	(7.07)	(8.89)	(8.17)	(7.65)	(7.11)
		Median	68.0	-5.0	68.5	-3.0	62.5	-4.5	67.0	-4.0
	Day 5	Min, Max	51, 90	-22, 10	52, 86	-24, 8	50, 89	-24, 7	50, 90	-24, 10
		n	79	79	40	40	34	34	153	153
		Mean	69.2	-2.7	71.6	-1.4	67.8	-2.0	69.5	-2.2
		(SD)	(7.49)	(6.70)	(9.10)	(8.02)	(8.32)	(7.11)	(8.18)	(7.13)
		Median	68.0	-2.0	71.5	-1.0	67.5	-1.0	69.0	-2.0
		Min, Max	53, 90	-23, 14	58, 93	-25, 13	50, 86	-20, 12	50, 93	-25, 14

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Diastolic Blood Pressure (mmHg)	Day 30	n	79	79	41	40	39	37	159	156
		Mean	70.3	-1.6	71.3	-1.5	67.8	-2.3	69.9	-1.7
		(SD)	(8.22)	(8.63)	(9.63)	(8.32)	(8.94)	(9.22)	(8.82)	(8.65)
		Median	70.0	-3.0	69.0	-0.5	68.0	-3.0	69.0	-2.0
	Day 6/Discharge Confinement	Min, Max	53, 93	-20, 23	57, 89	-28, 12	44, 86	-18, 21	44, 93	-28, 23
		n	79	79	41	40	39	37	159	156
		Mean	70.0	-1.9	72.4	-0.4	68.6	-1.4	70.3	-1.4
		(SD)	(7.55)	(8.06)	(7.59)	(6.85)	(7.38)	(7.50)	(7.60)	(7.61)
		Median	70.0	-2.0	72.0	1.0	69.0	-1.0	70.0	-1.0
		Min, Max	54, 93	-19, 17	59, 91	-24, 11	49, 86	-20, 15	49, 93	-24, 17

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Diastolic Blood Pressure (mmHg)	Day 60	n	79	79	41	40	39	37	159	156
		Mean	69.9	-2.0	68.8	-4.1	68.5	-1.5	69.2	-2.4
		(SD)	(8.75)	(8.94)	(11.30)	(9.83)	(8.33)	(8.04)	(9.34)	(8.98)
		Median	69.0	-2.0	67.0	-2.0	68.0	-2.0	68.0	-2.0
	Day 91/Discharge Ambulatory	Min, Max	52, 96	-22, 18	49, 91	-34, 17	54, 97	-18, 17	49, 97	-34, 18
		n	79	79	41	40	39	37	159	156
		Mean	70.7	-1.2	70.2	-2.6	70.4	0.5	70.5	-1.2
		(SD)	(9.35)	(8.23)	(8.95)	(8.13)	(8.35)	(11.22)	(8.96)	(9.01)
		Median	71.0	-3.0	71.0	-1.0	70.0	0.0	71.0	-2.0
		Min, Max	44, 97	-22, 18	53, 91	-25, 12	52, 90	-28, 28	44, 97	-28, 28

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Pulse Rate (BEATS/MIN)	Baseline	n	79		41		39		159	
		Mean	70.6		71.4		69.9		70.7	
		(SD)	(10.96)		(11.77)		(11.27)		(11.19)	
		Median	70.0		71.0		68.0		70.0	
	Day 1	Min, Max	45, 93		51, 99		52, 94		45, 99	
		n	78	78	40	40	29	29	147	147
		Mean	70.0	-0.7	73.9	2.1	67.2	-2.6	70.5	-0.3
		(SD)	(9.73)	(9.02)	(12.49)	(10.89)	(11.43)	(12.48)	(11.06)	(10.35)
		Median	70.0	-1.0	69.5	1.5	67.0	-3.0	69.0	-1.0
		Min, Max	51, 91	-23, 24	51, 109	-14, 32	52, 107	-23, 46	51, 109	-23, 46

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Pulse Rate (BEATS/MIN)	Day 2	n	79	79	40	40	34	34	153	153
		Mean	67.6	-3.0	72.4	0.5	63.3	-5.6	67.9	-2.7
		(SD)	(10.26)	(8.29)	(12.04)	(10.17)	(10.96)	(12.30)	(11.29)	(9.97)
		Median	67.0	-4.0	68.5	0.5	59.0	-5.0	66.0	-4.0
	Day 3	Min, Max	47, 104	-17, 24	54, 104	-16, 33	50, 96	-29, 26	47, 104	-29, 33
		n	79	79	40	40	34	34	153	153
		Mean	68.7	-1.9	72.6	0.8	63.2	-5.7	68.5	-2.1
		(SD)	(9.31)	(8.96)	(11.19)	(7.60)	(7.81)	(7.59)	(10.03)	(8.58)
		Median	68.0	-1.0	71.0	0.5	62.0	-5.0	68.0	-2.0
		Min, Max	51, 90	-25, 23	53, 103	-16, 28	47, 79	-24, 9	47, 103	-25, 28

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Pulse Rate (BEATS/MIN)	Day 4	n	79	79	40	40	34	34	153	153
		Mean	68.4	-2.3	72.4	0.6	64.1	-4.9	68.5	-2.1
		(SD)	(9.20)	(8.15)	(13.83)	(10.52)	(9.06)	(7.89)	(10.90)	(8.93)
		Median	67.0	-2.0	70.5	0.5	61.0	-4.0	67.0	-2.0
	Day 5	Min, Max	50, 91	-25, 24	52, 108	-14, 43	52, 89	-20, 17	50, 108	-25, 43
		n	79	79	40	40	34	34	153	153
		Mean	68.3	-2.3	73.1	1.2	61.4	-7.6	68.0	-2.5
		(SD)	(8.26)	(8.86)	(12.34)	(10.53)	(9.48)	(8.10)	(10.50)	(9.61)
		Median	68.0	-3.0	70.5	-2.0	60.0	-8.0	67.0	-3.0
		Min, Max	47, 94	-21, 23	52, 104	-16, 45	46, 83	-25, 8	46, 104	-25, 45

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Pulse Rate (BEATS/MIN)	Day 30	n	77	77	39	39	33	33	149	149
		Mean	68.7	-2.2	72.4	0.6	65.7	-3.7	69.0	-1.8
		(SD)	(10.28)	(8.98)	(12.33)	(11.01)	(9.60)	(11.88)	(10.90)	(10.27)
		Median	68.0	-3.0	69.0	0.0	65.0	-5.0	68.0	-3.0
	Day 6/Discharge Confinement	Min, Max	44, 93	-20, 36	49, 102	-23, 32	53, 84	-27, 22	44, 102	-27, 36
		n	79	79	40	40	34	34	153	153
		Mean	73.0	2.4	75.6	3.8	67.2	-1.8	72.4	1.8
		(SD)	(11.97)	(9.11)	(11.21)	(10.68)	(10.35)	(8.40)	(11.75)	(9.55)
		Median	73.0	2.0	74.0	3.0	66.5	-2.5	72.0	2.0
		Min, Max	47, 107	-16, 34	57, 111	-18, 28	47, 91	-19, 13	47, 111	-19, 34

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Pulse Rate (BEATS/MIN)	Day 60	n	74	74	37	37	31	31	142	142
		Mean	67.4	-3.4	69.0	-3.1	64.8	-4.6	67.3	-3.6
		(SD)	(10.91)	(10.26)	(11.74)	(9.75)	(8.51)	(7.92)	(10.69)	(9.61)
		Median	65.0	-2.5	67.0	-3.0	63.0	-5.0	65.0	-3.0
	Day 91/Discharge Ambulatory	Min, Max	47, 95	-27, 22	45, 94	-20, 28	47, 87	-20, 9	45, 95	-27, 28
		n	74	74	36	36	33	33	143	143
		Mean	66.2	-4.8	68.1	-4.2	65.2	-4.2	66.5	-4.5
		(SD)	(10.77)	(10.35)	(11.50)	(11.12)	(13.24)	(14.06)	(11.52)	(11.41)
		Median	64.5	-3.0	65.5	-4.0	62.0	-7.0	64.0	-4.0
		Min, Max	34, 95	-29, 25	48, 98	-27, 20	47, 99	-33, 35	34, 99	-33, 35

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Respiratory Rate (BREATHS/ MIN)	Baseline	n	79		41		39		159	
		Mean	16.7		16.3		16.5		16.5	
		(SD)	(2.40)		(2.49)		(2.41)		(2.41)	
		Median	16.0		16.0		16.0		16.0	
	Day 1	Min, Max	12, 24		10, 20		10, 20		10, 24	
		n	78	78	40	40	28	28	146	146
		Mean	16.5	-0.3	16.2	-0.2	16.3	-0.3	16.4	-0.3
		(SD)	(2.62)	(3.66)	(1.84)	(3.49)	(2.17)	(3.28)	(2.34)	(3.52)
		Median	16.0	0.0	16.0	0.0	16.0	0.0	16.0	0.0
		Min, Max	12, 24	-8, 10	12, 20	-6, 6	12, 22	-8, 6	12, 24	-8, 10

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Respiratory Rate (BREATHS/ MIN)	Day 2	n	77	77	39	39	34	34	150	150
		Mean	16.0	-0.7	15.7	-0.6	15.3	-1.2	15.8	-0.8
		(SD)	(3.02)	(3.61)	(2.76)	(3.47)	(2.65)	(3.20)	(2.87)	(3.47)
		Median	16.0	0.0	16.0	0.0	16.0	-2.0	16.0	0.0
	Day 3	Min, Max	12, 22	-8, 6	10, 22	-6, 6	10, 22	-10, 6	10, 22	-10, 6
		n	79	79	40	40	34	34	153	153
		Mean	16.6	-0.1	16.2	-0.2	16.1	-0.4	16.4	-0.2
		(SD)	(2.13)	(2.82)	(2.40)	(3.52)	(2.12)	(3.65)	(2.20)	(3.19)
		Median	16.0	0.0	16.0	0.0	16.0	0.0	16.0	0.0
		Min, Max	12, 24	-6, 10	10, 20	-8, 8	12, 20	-8, 10	10, 24	-8, 10

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Respiratory Rate (BREATHS/ MIN)	Day 4	n	79	79	40	40	34	34	153	153
		Mean	16.3	-0.4	16.4	0.1	16.0	-0.5	16.3	-0.3
		(SD)	(2.84)	(3.84)	(2.23)	(2.99)	(2.79)	(3.72)	(2.67)	(3.60)
		Median	16.0	0.0	16.0	0.0	16.0	0.0	16.0	0.0
	Day 5	Min, Max	10, 24	-8, 12	12, 22	-8, 6	10, 24	-6, 12	10, 24	-8, 12
		n	78	78	40	40	34	34	152	152
		Mean	16.8	0.1	16.2	-0.2	15.6	-0.9	16.3	-0.2
		(SD)	(2.44)	(3.52)	(2.60)	(3.83)	(2.41)	(3.69)	(2.51)	(3.64)
		Median	16.0	0.0	16.0	0.0	16.0	-1.5	16.0	0.0
		Min, Max	12, 24	-10, 8	12, 24	-8, 10	12, 20	-8, 8	12, 24	-10, 10

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Respiratory Rate (BREATHS/ MIN)	Day 30	n	77	77	39	39	33	33	149	149
		Mean	16.1	-0.6	15.8	-0.6	15.3	-1.3	15.8	-0.8
		(SD)	(2.25)	(3.40)	(2.53)	(3.63)	(2.06)	(3.08)	(2.29)	(3.38)
		Median	16.0	0.0	16.0	-2.0	16.0	-2.0	16.0	-2.0
	Day 6/Discharge Confinement	Min, Max	12, 22	-8, 8	12, 22	-7, 10	12, 20	-8, 6	12, 22	-8, 10
		n	79	79	39	39	34	34	152	152
		Mean	15.9	-0.8	16.6	0.3	16.0	-0.5	16.1	-0.4
		(SD)	(2.09)	(2.73)	(2.79)	(3.46)	(2.09)	(2.61)	(2.29)	(2.92)
		Median	16.0	0.0	16.0	0.0	16.0	0.0	16.0	0.0
		Min, Max	12, 22	-8, 4	12, 24	-6, 8	12, 24	-6, 4	12, 24	-8, 8

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.20 Summary of Supine Vital Signs - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Respiratory Rate (BREATHS/ MIN)	Day 60	n	74	74	36	36	31	31	141	141
		Mean	16.7	0.0	16.5	0.2	16.4	-0.1	16.6	0.1
		(SD)	(2.42)	(3.15)	(1.75)	(2.74)	(2.22)	(3.37)	(2.21)	(3.08)
		Median	16.0	0.0	16.0	0.0	16.0	0.0	16.0	0.0
	Day 91/Discharge Ambulatory	Min, Max	12, 24	-6, 10	12, 20	-6, 6	12, 20	-8, 6	12, 24	-8, 10
		n	74	74	36	36	33	33	143	143
		Mean	16.5	-0.3	16.2	0.0	16.6	0.1	16.4	-0.1
		(SD)	(2.45)	(3.24)	(2.11)	(3.28)	(2.10)	(3.30)	(2.28)	(3.24)
		Median	16.0	0.0	16.0	0.0	16.0	0.0	16.0	0.0
		Min, Max	12, 24	-8, 10	12, 20	-6, 8	10, 20	-6, 8	10, 24	-8, 10

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Interpretation	Baseline	n	79	41	39	159
		Normal	72 (91.1%)	37 (90.2%)	35 (89.7%)	144 (90.6%)
		Abnormal NCS	7 (8.9%)	4 (9.8%)	4 (10.3%)	15 (9.4%)
		Abnormal CS	0	0	0	0
	Day 6/Discharge Confinement	n	79	40	35	154
		Normal	71 (89.9%)	39 (97.5%)	30 (85.7%)	140 (90.9%)
		Abnormal NCS	8 (10.1%)	1 (2.5%)	5 (14.3%)	14 (9.1%)
		Abnormal CS	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Interpretation	Day 30	n	77	39	33	149
		Normal	68 (88.3%)	35 (89.7%)	31 (93.9%)	134 (89.9%)
		Abnormal NCS	9 (11.7%)	4 (10.3%)	2 (6.1%)	15 (10.1%)
		Abnormal CS	0	0	0	0
	Day 60	n	74	37	31	142
		Normal	67 (90.5%)	34 (91.9%)	25 (80.6%)	126 (88.7%)
		Abnormal NCS	7 (9.5%)	3 (8.1%)	6 (19.4%)	16 (11.3%)
		Abnormal CS	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Interpretation	Day 91/Discharge Ambulatory	n	73	36	33	142
		Normal	68 (93.2%)	35 (97.2%)	30 (90.9%)	133 (93.7%)
		Abnormal NCS	5 (6.8%)	1 (2.8%)	3 (9.1%)	9 (6.3%)
		Abnormal CS	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Heart Rate (Beats/min)	Baseline	n	79		41		39		159	
		Mean	64.0		64.9		64.9		64.5	
		(SD)	(10.12)		(12.58)		(11.12)		(10.98)	
		Median	63.0		64.0		66.0		64.0	
		Min, Max	40, 90		43, 96		46, 89		40, 96	
	Day 6/Discharge Confinement	n	79	79	40	40	35	35	154	154
		Mean	72.8	8.8	74.6	9.5	68.1	3.5	72.2	7.8
		(SD)	(11.25)	(11.49)	(11.61)	(10.53)	(11.54)	(9.08)	(11.58)	(10.92)
		Median	73.0	8.0	74.0	8.0	69.0	3.0	72.0	7.0
		Min, Max	46, 95	-28, 34	53, 109	-22, 35	46, 92	-20, 22	46, 109	-28, 35

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Heart Rate (Beats/min)	Day 30	n	77	77	39	39	33	33	149	149
		Mean	69.0	5.4	72.5	7.4	64.9	0.4	69.0	4.8
		(SD)	(11.27)	(10.27)	(12.67)	(9.85)	(8.49)	(8.27)	(11.36)	(10.01)
		Median	69.0	5.0	71.0	8.0	63.0	0.0	69.0	5.0
		Min, Max	43, 96	-23, 32	51, 101	-15, 24	50, 84	-16, 20	43, 101	-23, 32
	Day 60	n	74	74	37	37	31	31	142	142
		Mean	67.2	3.2	69.9	4.5	64.3	-0.6	67.3	2.7
		(SD)	(10.72)	(9.84)	(11.54)	(11.47)	(9.85)	(9.06)	(10.86)	(10.23)
		Median	66.0	2.5	70.0	5.0	62.0	0.0	66.5	2.5
		Min, Max	47, 93	-21, 31	44, 100	-28, 30	46, 90	-21, 26	44, 100	-28, 31

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Heart Rate (Beats/min)	Day 91/Discharge Ambulatory	n	73	73	36	36	33	33	142	142
		Mean	65.9	1.5	68.1	2.4	63.6	-0.8	65.9	1.2
		(SD)	(10.40)	(10.45)	(11.62)	(10.54)	(11.95)	(12.33)	(11.12)	(10.92)
		Median	65.0	1.0	68.0	1.5	62.0	-2.0	65.0	0.0
		Min, Max	36, 95	-28, 36	50, 93	-17, 25	45, 96	-30, 45	36, 96	-30, 45

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
PR Duration (msec)	Baseline	n	79		41		39		159	
		Mean	156.5		154.7		155.8		155.8	
		(SD)	(18.51)		(22.48)		(19.92)		(19.82)	
		Median	155.0		151.0		157.0		154.0	
		Min, Max	118, 204		122, 219		114, 196		114, 219	
	Day 6/Discharge Confinement	n	79	79	40	40	35	35	154	154
		Mean	157.3	0.8	155.8	0.9	159.2	1.6	157.3	1.0
		(SD)	(18.38)	(13.25)	(20.21)	(11.66)	(18.29)	(12.04)	(18.76)	(12.51)
		Median	152.0	4.0	154.0	0.0	160.0	-1.0	155.0	2.0
		Min, Max	124, 209	-50, 28	121, 209	-29, 43	116, 196	-19, 40	116, 209	-50, 43

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
PR Duration (msec)	Day 30	n	77	77	39	39	33	33	149	149
		Mean	156.0	-0.6	155.0	0.5	158.3	0.5	156.3	-0.1
		(SD)	(18.40)	(9.24)	(25.02)	(12.42)	(24.12)	(14.87)	(21.49)	(11.47)
		Median	153.0	-1.0	148.0	-1.0	160.0	0.0	152.0	-1.0
		Min, Max	129, 204	-26, 21	117, 216	-25, 45	100, 212	-59, 22	100, 216	-59, 45
	Day 60	n	74	74	37	37	31	31	142	142
		Mean	156.6	-0.6	153.9	-0.4	161.1	3.9	156.9	0.4
		(SD)	(20.60)	(12.49)	(20.10)	(11.86)	(23.61)	(13.11)	(21.15)	(12.52)
		Median	155.5	-0.5	149.0	1.0	159.0	5.0	155.0	1.0
		Min, Max	123, 240	-35, 36	120, 211	-23, 34	119, 231	-25, 35	119, 240	-35, 36

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
PR Duration (msec)	Day 91/Discharge Ambulatory	n	73	73	36	36	33	33	142	142
		Mean	156.9	0.0	153.8	0.0	159.7	1.9	156.8	0.5
		(SD)	(18.53)	(9.76)	(20.08)	(12.24)	(21.46)	(9.93)	(19.60)	(10.43)
		Median	154.0	-1.0	147.0	2.0	161.0	2.0	152.0	1.0
		Min, Max	128, 207	-36, 31	115, 200	-29, 36	116, 213	-22, 23	115, 213	-36, 36

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QT Duration (msec)	Baseline	n	79		41		39		159	
		Mean	396.6		397.5		388.9		395.0	
		(SD)	(27.95)		(28.34)		(29.36)		(28.43)	
		Median	395.0		397.0		385.0		394.0	
		Min, Max	341, 464		329, 446		346, 463		329, 464	
	Day 6/Discharge Confinement	n	79	79	40	40	35	35	154	154
		Mean	375.3	-21.3	372.3	-24.7	382.2	-7.7	376.1	-19.1
		(SD)	(26.76)	(23.94)	(20.87)	(24.79)	(28.19)	(18.32)	(25.79)	(23.75)
		Median	370.0	-21.0	371.0	-24.5	378.0	-8.0	373.5	-18.0
		Min, Max	322, 451	-69, 48	329, 424	-86, 30	329, 437	-42, 31	322, 451	-86, 48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QT Duration (msec)	Day 30	n	77	77	39	39	33	33	149	149
		Mean	383.5	-13.8	379.6	-16.9	389.6	0.2	383.8	-11.5
		(SD)	(25.28)	(20.27)	(23.86)	(21.72)	(24.56)	(18.44)	(24.84)	(21.13)
		Median	381.0	-14.0	380.0	-18.0	384.0	0.0	381.0	-11.0
		Min, Max	334, 450	-58, 42	331, 435	-59, 39	355, 437	-33, 42	331, 450	-59, 42
	Day 60	n	74	74	37	37	31	31	142	142
		Mean	390.1	-7.8	385.1	-11.2	392.0	3.1	389.2	-6.3
		(SD)	(27.51)	(19.13)	(28.00)	(25.14)	(25.17)	(16.71)	(27.08)	(20.91)
		Median	385.0	-9.0	378.0	-13.0	389.0	2.0	385.0	-9.0
		Min, Max	340, 460	-53, 34	343, 456	-81, 47	355, 446	-35, 39	340, 460	-81, 47

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QT Duration (msec)	Day 91/Discharge Ambulatory	n	73	73	36	36	33	33	142	142
		Mean	387.9	-8.6	386.6	-8.7	391.4	1.9	388.4	-6.2
		(SD)	(24.10)	(22.92)	(24.67)	(21.37)	(28.54)	(25.06)	(25.21)	(23.33)
		Median	386.0	-10.0	383.5	-9.0	394.0	6.0	386.5	-7.0
		Min, Max	320, 447	-63, 41	346, 427	-61, 26	325, 449	-70, 48	320, 449	-70, 48

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QTcB - Bazett's Correction Formula (msec)	Baseline	n	79		41		39		159	
		Mean	407.8		410.3		403.3		407.3	
		(SD)	(22.34)		(22.52)		(23.26)		(22.61)	
		Median	408.0		413.0		408.0		409.0	
		Min, Max	361, 471		349, 456		346, 446		346, 471	
	Day 6/Discharge Confinement	n	79	79	40	40	35	35	154	154
		Mean	411.1	3.4	413.6	3.4	404.8	1.5	410.4	2.9
		(SD)	(20.71)	(18.75)	(20.63)	(15.37)	(23.33)	(18.31)	(21.41)	(17.74)
		Median	411.0	4.0	411.5	5.0	406.0	2.0	410.5	3.0
		Min, Max	364, 475	-73, 51	368, 448	-23, 41	352, 446	-45, 63	352, 475	-73, 63

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QTcB - Bazett's Correction Formula (msec)	Day 30	n	77	77	39	39	33	33	149	149
		Mean	409.4	2.0	414.9	4.9	404.5	1.6	409.8	2.7
		(SD)	(25.07)	(21.26)	(20.07)	(17.80)	(24.61)	(16.62)	(23.88)	(19.37)
		Median	412.0	2.0	414.0	6.0	403.0	6.0	412.0	5.0
		Min, Max	357, 475	-81, 58	376, 456	-58, 39	368, 464	-35, 36	357, 475	-81, 58
	Day 60	n	74	74	37	37	31	31	142	142
		Mean	410.7	1.9	413.4	3.1	403.9	0.2	409.9	1.8
		(SD)	(22.61)	(20.30)	(19.68)	(20.60)	(24.11)	(20.67)	(22.33)	(20.34)
		Median	411.5	0.5	414.0	4.0	401.0	-3.0	411.0	2.0
		Min, Max	368, 466	-77, 55	377, 451	-55, 42	341, 454	-41, 59	341, 466	-77, 59

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QTcB - Bazett's Correction Formula (msec)	Day 91/Discharge Ambulatory	n	73	73	36	36	33	33	142	142
		Mean	404.8	-3.9	409.8	-0.5	400.8	-2.1	405.1	-2.6
		(SD)	(21.70)	(18.45)	(22.48)	(19.47)	(27.21)	(20.13)	(23.32)	(19.03)
		Median	402.0	-4.0	406.5	-0.5	398.0	-3.0	403.0	-3.0
		Min, Max	348, 460	-73, 33	364, 455	-62, 36	350, 460	-66, 61	348, 460	-73, 61

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QTcF - Fridericia's Correction Formula (msec)	Baseline	n	79		41		39		159	
		Mean	403.6		405.3		397.9		402.6	
		(SD)	(19.20)		(16.89)		(19.86)		(18.89)	
		Median	402.0		404.0		398.0		402.0	
		Min, Max	364, 459		363, 434		359, 438		359, 459	
	Day 6/Discharge Confinement	n	79	79	40	40	35	35	154	154
		Mean	398.4	-5.2	398.9	-6.2	396.7	-1.7	398.1	-4.6
		(SD)	(17.30)	(13.49)	(15.15)	(12.16)	(19.47)	(14.03)	(17.21)	(13.30)
		Median	396.0	-5.0	398.0	-6.0	400.0	-2.0	397.0	-5.0
		Min, Max	356, 449	-57, 29	363, 430	-31, 22	349, 425	-45, 41	349, 449	-57, 41

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QTcF - Fridericia's Correction Formula (msec)	Day 30	n	77	77	39	39	33	33	149	149
		Mean	400.0	-3.6	402.2	-2.5	399.2	1.3	400.4	-2.2
		(SD)	(19.51)	(14.59)	(14.18)	(12.73)	(21.42)	(12.16)	(18.65)	(13.66)
		Median	400.0	-4.0	401.0	-2.0	399.0	5.0	400.0	-2.0
		Min, Max	362, 464	-55, 33	373, 428	-41, 28	365, 448	-29, 16	362, 464	-55, 33
	Day 60	n	74	74	37	37	31	31	142	142
		Mean	403.3	-1.4	403.1	-1.7	399.7	1.5	402.5	-0.8
		(SD)	(19.13)	(13.74)	(15.85)	(13.56)	(19.95)	(14.50)	(18.45)	(13.81)
		Median	403.5	-1.5	402.0	0.0	401.0	2.0	402.5	-0.5
		Min, Max	361, 455	-53, 35	369, 438	-35, 22	346, 440	-23, 34	346, 455	-53, 35

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QTcF - Fridericia's Correction Formula (msec)	Day 91/Discharge Ambulatory	n	73	73	36	36	33	33	142	142
		Mean	398.6	-5.5	401.4	-3.1	397.2	-0.7	399.0	-3.8
		(SD)	(16.98)	(13.84)	(16.91)	(13.24)	(22.14)	(14.31)	(18.22)	(13.84)
		Median	400.0	-6.0	399.5	-2.5	399.0	-2.0	400.0	-4.5
		Min, Max	362, 442	-57, 24	370, 444	-43, 25	357, 436	-43, 36	357, 444	-57, 36

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QRS Duration (msec)	Baseline	n	79		41		39		159	
		Mean	93.2		91.3		91.1		92.2	
		(SD)	(8.56)		(8.02)		(8.11)		(8.32)	
		Median	93.0		91.0		89.0		92.0	
		Min, Max	73, 112		77, 109		78, 112		73, 112	
	Day 6/Discharge Confinement	n	79	79	40	40	35	35	154	154
		Mean	95.6	2.4	91.1	-0.3	94.6	3.3	94.2	1.9
		(SD)	(9.01)	(6.98)	(10.07)	(6.47)	(10.70)	(7.77)	(9.81)	(7.13)
		Median	94.0	2.0	89.5	-2.0	91.0	1.0	93.0	1.0
		Min, Max	73, 120	-13, 22	74, 118	-11, 17	82, 125	-15, 22	73, 125	-15, 22

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QRS Duration (msec)	Day 30	n	77	77	39	39	33	33	149	149
		Mean	93.8	0.5	91.6	0.4	91.3	0.9	92.7	0.5
		(SD)	(8.53)	(5.81)	(8.86)	(7.28)	(8.79)	(4.87)	(8.69)	(6.01)
		Median	93.0	1.0	92.0	-1.0	89.0	1.0	92.0	0.0
		Min, Max	75, 114	-17, 15	77, 116	-12, 17	78, 114	-9, 14	75, 116	-17, 17
	Day 60	n	74	74	37	37	31	31	142	142
		Mean	94.6	1.8	91.0	-0.1	92.4	2.3	93.2	1.4
		(SD)	(8.06)	(6.14)	(8.39)	(6.70)	(10.39)	(6.22)	(8.78)	(6.33)
		Median	93.0	1.0	92.0	-1.0	89.0	1.0	92.0	1.0
		Min, Max	76, 117	-13, 17	76, 110	-12, 14	78, 124	-9, 18	76, 124	-13, 18

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.21 Summary of ECG Measurements - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
QRS Duration (msec)	Day 91/Discharge Ambulatory	n	73	73	36	36	33	33	142	142
		Mean	94.7	1.8	91.5	0.6	92.8	2.4	93.4	1.6
		(SD)	(8.34)	(7.33)	(7.93)	(6.99)	(8.71)	(7.74)	(8.38)	(7.32)
		Median	94.0	2.0	92.0	-0.5	90.0	2.0	93.0	2.0
		Min, Max	73, 114	-21, 18	78, 106	-12, 16	72, 118	-18, 15	72, 118	-21, 18

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: NCS = not clinically significant; CS = clinically significant.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Interpretation	Screening	n	1	1	4	0	6
		Normal	1 (100.0%)	1 (100.0%)	4 (100.0%)	0	6 (100.0%)
		Abnormal NCS	0	0	0	0	0
		Abnormal CS	0	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Interpretation	Day 0	n	78	40	35	0	153
		Normal	32 (41.0%)	17 (42.5%)	21 (60.0%)	0	70 (45.8%)
		Abnormal NCS	45 (57.7%)	22 (55.0%)	14 (40.0%)	0	81 (52.9%)
		Abnormal CS	1 (1.3%)	1 (2.5%)	0	0	2 (1.3%)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Interpretation (with bronchodilator)	Screening	n	79	41	39	4	163
		Normal	67 (84.8%)	39 (95.1%)	35 (89.7%)	4 (100.0%)	145 (89.0%)
		Abnormal NCS	12 (15.2%)	2 (4.9%)	4 (10.3%)	0	18 (11.0%)
		Abnormal CS	0	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Interpretation (with bronchodilator)	Day 0	n	78	40	35	0	153
		Normal	63 (80.8%)	35 (87.5%)	30 (85.7%)	0	128 (83.7%)
		Abnormal NCS	15 (19.2%)	5 (12.5%)	5 (14.3%)	0	25 (16.3%)
		Abnormal CS	0	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Best measured FVC value Screening (with bronchodilator) (L)		n	79	41	39	4	163
		Mean	4.324	4.665	4.401	4.393	4.430
		(SD)	(1.0611)	(0.8653)	(1.0451)	(1.5117)	(1.0223)
		95% CI of Mean	4.086, 4.562	4.391, 4.938	4.061, 4.740	1.987, 6.798	4.271, 4.588
		Median	4.290	4.750	4.360	4.240	4.450
		Min, Max	2.32, 6.57	2.27, 6.42	2.51, 6.43	2.77, 6.32	2.27, 6.57

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Best measured FVC value Day 0 (with bronchodilator) (L)		n	78	40	35	0	153
		Mean	4.265	4.676	4.204		4.359
		(SD)	(1.0771)	(0.8453)	(0.9794)		(1.0110)
		95% CI of Mean	4.022, 4.509	4.405, 4.947	3.867, 4.541		4.197, 4.521
		Median	4.265	4.735	4.190		4.380
		Min, Max	2.23, 6.41	2.38, 6.35	2.45, 5.99		2.23, 6.41

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Percent of predicted FVC value (with bronchodilator) (%)	Screening	n	79	41	39	4	163
		Mean	97.0	101.0	99.4	88.8	98.4
		(SD)	(15.66)	(13.99)	(14.82)	(9.00)	(14.99)
		95% CI of Mean	93.4, 100.5	96.5, 105.5	94.5, 104.2	74.4, 103.1	96.0, 100.7
		Median	98.0	103.0	101.0	85.5	99.0
		Min, Max	64, 134	68, 131	64, 144	82, 102	64, 144

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Percent of predicted FVC value (with bronchodilator) (%)	Day 0	n	78	40	35	0	153
		Mean	94.6	100.2	94.3		96.0
		(SD)	(13.80)	(14.67)	(13.25)		(14.04)
		95% CI of Mean	91.5, 97.8	95.4, 104.9	89.7, 98.9		93.7, 98.3
		Median	96.0	99.0	94.0		96.0
		Min, Max	62, 122	71, 128	64, 125		62, 128

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Best measured FEV1 value (with bronchodilator) (L)	Screening	n	79	41	39	4	163
		Mean	3.421	3.700	3.473	3.560	3.507
		(SD)	(0.8526)	(0.7118)	(0.8127)	(1.1525)	(0.8173)
		95% CI of Mean	3.229, 3.612	3.475, 3.925	3.209, 3.737	1.726, 5.394	3.380, 3.634
		Median	3.450	3.800	3.480	3.455	3.570
		Min, Max	1.85, 5.13	1.98, 5.09	2.09, 5.13	2.27, 5.06	1.85, 5.13

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Best measured FEV1 value (with bronchodilator) (L)	Day 0	n	78	40	35	0	153
		Mean	3.379	3.672	3.331		3.445
		(SD)	(0.8378)	(0.7051)	(0.8155)		(0.8067)
		95% CI of Mean	3.190, 3.569	3.446, 3.898	3.050, 3.611		3.316, 3.574
		Median	3.405	3.725	3.360		3.450
		Min, Max	1.83, 5.18	2.05, 5.10	1.90, 4.85		1.83, 5.18

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Percent of predicted FEV1 value (with bronchodilator) (%)	Screening	n	79	41	39	4	163
		Mean	94.2	97.5	96.3	90.5	95.4
		(SD)	(12.86)	(12.59)	(11.88)	(9.15)	(12.49)
		95% CI of Mean	91.3, 97.2	93.5, 101.5	92.4, 100.2	75.9, 105.1	93.5, 97.4
		Median	96.0	98.0	95.0	90.0	96.0
		Min, Max	62, 120	69, 126	64, 123	80, 102	62, 126

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Percent of predicted FEV1 value (with bronchodilator) (%)	Day 0	n	78	40	35	0	153
		Mean	93.4	96.6	92.7		94.1
		(SD)	(12.66)	(13.81)	(13.44)		(13.15)
		95% CI of Mean	90.5, 96.3	92.1, 101.1	88.0, 97.4		91.9, 96.2
		Median	94.0	95.0	92.0		94.0
		Min, Max	60, 122	71, 126	63, 123		60, 126

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Calculated ratio between FEV1/FVC (with bronchodilator) (RATIO)	Screening	n	79	41	39	4	163
		Mean	0.794	0.795	0.794	0.815	0.795
		(SD)	(0.0656)	(0.0555)	(0.0677)	(0.0500)	(0.0630)
		95% CI of Mean	0.779, 0.809	0.777, 0.813	0.771, 0.816	0.735, 0.895	0.784, 0.805
		Median	0.800	0.800	0.790	0.810	0.800
		Min, Max	0.54, 0.90	0.68, 0.90	0.59, 0.91	0.76, 0.88	0.54, 0.91

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Mid expiratory flow 25-75 (with bronchodilator) (L/s)	Screening	n	79	41	39	4	163
		Mean	3.298	3.670	3.334	3.563	3.407
		(SD)	(1.2482)	(1.1748)	(1.2422)	(0.9943)	(1.2233)
		95% CI of Mean	3.018, 3.578	3.299, 4.042	2.931, 3.737	1.980, 5.145	3.217, 3.596
		Median	3.140	3.500	3.240	3.525	3.370
		Min, Max	0.32, 6.85	1.51, 6.44	0.91, 6.17	2.48, 4.72	0.32, 6.85

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Mid expiratory flow 25-75 (with bronchodilator) (L/s)	Day 0	n	78	40	35	0	153
		Mean	3.219	3.390	3.173		3.253
		(SD)	(1.0909)	(1.0577)	(0.9799)		(1.0544)
		95% CI of Mean	2.973, 3.466	3.051, 3.729	2.836, 3.510		3.084, 3.422
		Median	3.210	3.390	3.260		3.230
		Min, Max	0.96, 6.17	1.50, 5.13	1.47, 4.81		0.96, 6.17

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Best measured FVC value Screening (L)		n	79	41	39	0	159
		Mean	4.469	4.711	4.423		4.520
		(SD)	(1.1054)	(0.9132)	(1.0332)		(1.0412)
		95% CI of Mean	4.221, 4.718	4.422, 4.999	4.088, 4.758		4.357, 4.684
		Median	4.350	4.800	4.340		4.550
		Min, Max	2.51, 6.61	2.28, 6.60	2.59, 6.79		2.28, 6.79

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Percent of predicted FVC value (%)	Screening	n	79	41	39	0	159
		Mean	100.0	101.8	100.1		100.5
		(SD)	(15.48)	(14.16)	(16.52)		(15.34)
		95% CI of Mean	96.5, 103.6	97.3, 106.3	94.6, 105.5		98.1, 103.0
		Median	101.0	103.0	99.0		101.0
		Min, Max	63, 130	68, 134	65, 141		63, 141

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Best measured FEV1 value (L)	Screening	n	79	41	39	0	159
		Mean	3.356	3.624	3.379		3.431
		(SD)	(0.8344)	(0.6974)	(0.7868)		(0.7930)
		95% CI of Mean	3.168, 3.543	3.403, 3.845	3.124, 3.635		3.306, 3.555
		Median	3.300	3.710	3.300		3.430
		Min, Max	1.87, 5.17	1.94, 5.00	2.07, 5.04		1.87, 5.17

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Percent of predicted FEV1 value (%)	Screening	n	79	41	39	0	159
		Mean	92.5	95.4	93.8		93.6
		(SD)	(12.52)	(12.00)	(11.48)		(12.12)
		95% CI of Mean	89.7, 95.4	91.6, 99.2	90.0, 97.5		91.6, 95.5
		Median	95.0	95.0	93.0		95.0
		Min, Max	61, 122	67, 124	64, 122		61, 124

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Calculated ratio between FEV1/FVC (RATIO)	Screening	n	79	41	39	0	159
		Mean	0.755	0.772	0.768		0.762
		(SD)	(0.0719)	(0.0646)	(0.0718)		(0.0700)
		95% CI of Mean	0.738, 0.772	0.751, 0.793	0.744, 0.791		0.751, 0.774
		Median	0.770	0.770	0.770		0.770
		Min, Max	0.52, 0.89	0.67, 0.93	0.58, 0.90		0.52, 0.93

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Ratio between FEV1/FVC Day 0 (Derived) (RATIO)		n	78	40	35	0	153
		Mean	0.796	0.787	0.792		0.793
		(SD)	(0.0538)	(0.0647)	(0.0522)		(0.0562)
		95% CI of Mean	0.783, 0.809	0.766, 0.808	0.773, 0.810		0.783, 0.802
		Median	0.800	0.785	0.790		0.790
		Min, Max	0.66, 0.90	0.61, 0.91	0.68, 0.95		0.61, 0.95

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Mid expiratory flow 25-75 (L/s)	Screening	n	79	41	39	0	159
		Mean	2.826	3.286	2.971		2.980
		(SD)	(1.1426)	(1.1298)	(1.2209)		(1.1672)
		95% CI of Mean	2.569, 3.082	2.929, 3.643	2.575, 3.368		2.797, 3.163
		Median	2.690	3.140	2.790		2.820
		Min, Max	0.43, 5.64	1.61, 6.49	0.48, 6.35		0.43, 6.49

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Diffusion Capacity for Lung CO (mL/min/mmHg)	Day 0	n	76	40	33	0	149
		Mean	23.290	24.379	23.118		23.545
		(SD)	(5.9644)	(6.2093)	(6.1601)		(6.0543)
		95% CI of Mean	21.927, 24.654	22.393, 26.366	20.934, 25.303		22.564, 24.525
		Median	23.600	24.235	24.420		24.010
		Min, Max	12.79, 36.66	12.20, 46.10	11.41, 32.94		11.41, 46.10

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Rate Constant of CO (mmol/min/kPa/L)	Day 0	n	76	40	33	0	149
		Mean	1.376	1.344	1.325		1.356
		(SD)	(0.2680)	(0.2527)	(0.2667)		(0.2628)
		95% CI of Mean	1.314, 1.437	1.263, 1.425	1.230, 1.420		1.313, 1.399
		Median	1.355	1.290	1.320		1.340
		Min, Max	0.75, 2.01	0.93, 1.95	0.79, 2.05		0.75, 2.05

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

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Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Inspiratory Capacity (L)	Day 0	n	78	40	35	0	153
		Mean	2.861	2.984	2.957		2.915
		(SD)	(0.9661)	(0.8578)	(0.9802)		(0.9379)
		95% CI of Mean	2.643, 3.079	2.709, 3.259	2.620, 3.294		2.765, 3.065
		Median	2.820	2.955	2.820		2.850
		Min, Max	0.49, 5.90	0.48, 4.33	0.94, 5.04		0.48, 5.90

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Residual Volume (L)	Day 0	n	78	40	35	0	153
		Mean	3.083	3.158	2.951		3.073
		(SD)	(1.2369)	(0.9214)	(0.6550)		(1.0460)
		95% CI of Mean	2.804, 3.363	2.863, 3.453	2.726, 3.177		2.905, 3.240
		Median	2.830	3.240	3.030		3.010
		Min, Max	1.41, 8.77	1.72, 6.04	1.24, 4.38		1.24, 8.77

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Total Lung Capacity (L)	Day 0	n	78	40	35	0	153
		Mean	5.944	6.142	5.908		5.988
		(SD)	(1.7602)	(1.1831)	(1.3833)		(1.5380)
		95% CI of Mean	5.547, 6.342	5.763, 6.521	5.433, 6.384		5.742, 6.234
		Median	5.915	6.195	5.800		5.880
		Min, Max	2.74, 13.07	3.19, 8.92	2.46, 8.94		2.46, 13.07

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Pre-Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Product Use (N=5)	Overall Safety (N=165)
			Raw value	Raw value	Raw value	Raw value	Raw value
Vital Capacity (L)	Day 0	n	78	40	35	0	153
		Mean	4.335	4.732	4.272		4.424
		(SD)	(1.0543)	(0.8614)	(1.0123)		(1.0085)
		95% CI of Mean	4.097, 4.573	4.456, 5.008	3.924, 4.620		4.263, 4.586
		Median	4.360	4.810	4.310		4.450
		Min, Max	2.37, 6.44	2.39, 6.35	2.45, 6.39		2.37, 6.44

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant.

Note: 'Product Test' refers to all subjects who tested the THS product on Day -2 but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Interpretation	Baseline	n	79	41	39	159
		Normal	33 (41.8%)	18 (43.9%)	25 (64.1%)	76 (47.8%)
		Abnormal NCS	45 (57.0%)	22 (53.7%)	14 (35.9%)	81 (50.9%)
		Abnormal CS	1 (1.3%)	1 (2.4%)	0	2 (1.3%)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

Appendix 15.3.6.11

Study ID:ZRHM-REXA-08-US Program:t_spiro.sas Status: Final

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**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Interpretation	Day 6/Discharge Confinement	n	78	40	33	151
		Normal	38 (48.7%)	23 (57.5%)	17 (51.5%)	78 (51.7%)
		Abnormal NCS	37 (47.4%)	16 (40.0%)	15 (45.5%)	68 (45.0%)
		Abnormal CS	3 (3.8%)	1 (2.5%)	1 (3.0%)	5 (3.3%)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

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Study ID: ZRHM-REXA-08-US Program: t_spiro.sas Status: Final

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**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Interpretation	Day 91/Discharge n Ambulatory		74	34	31	139
		Normal	38 (51.4%)	17 (50.0%)	14 (45.2%)	69 (49.6%)
		Abnormal NCS	34 (45.9%)	17 (50.0%)	16 (51.6%)	67 (48.2%)
		Abnormal CS	2 (2.7%)	0	1 (3.2%)	3 (2.2%)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

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Study ID: ZRHM-REXA-08-US Program: t_spiro.sas Status: Final

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**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Interpretation (with bronchodilator)	Baseline	n	79	41	39	159
		Normal	64 (81.0%)	36 (87.8%)	34 (87.2%)	134 (84.3%)
		Abnormal NCS	15 (19.0%)	5 (12.2%)	5 (12.8%)	25 (15.7%)
		Abnormal CS	0	0	0	0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

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**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Interpretation (with bronchodilator)	Day 6/Discharge Confinement	n	78	40	33	151
		Normal	63 (80.8%)	36 (90.0%)	29 (87.9%)	128 (84.8%)
		Abnormal NCS	14 (17.9%)	4 (10.0%)	4 (12.1%)	22 (14.6%)
		Abnormal CS	1 (1.3%)	0	0	1 (0.7%)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

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**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Interpretation (with bronchodilator)	Day 91/Discharge n Ambulatory		74	34	31	139
		Normal	57 (77.0%)	28 (82.4%)	24 (77.4%)	109 (78.4%)
		Abnormal NCS	16 (21.6%)	6 (17.6%)	7 (22.6%)	29 (20.9%)
		Abnormal CS	1 (1.4%)	0	0	1 (0.7%)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

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**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Best measured FVC value (with bronchodilator) (L)	Baseline	n	79		41		39		159	
		Mean	4.271		4.630		4.304		4.371	
		(SD)	(1.0713)		(0.8857)		(1.0139)		(1.0178)	
		95% CI of	4.030,		4.350,		3.974,		4.212,	
		Mean	4.511		4.910		4.633		4.531	
		Median	4.280		4.710		4.420		4.420	
		Min, Max	2.23, 6.41		2.38, 6.35		2.45, 5.99		2.23, 6.41	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Best measured FVC value (with bronchodilator) (L)	Day 6/Discharge Confinement	n	78	78	40	40	33	33	151	151
		Mean	4.281	0.015	4.632	-0.044	4.243	0.078	4.366	0.013
		(SD)	(1.0529)	(0.1951)	(0.8249)	(0.2067)	(0.9889)	(0.1972)	(0.9903)	(0.2018)
		95% CI of	4.043,	-0.029,	4.368,	-0.111,	3.892,	0.007,	4.206,	-0.020,
		Mean	4.519	0.060	4.897	0.023	4.594	0.148	4.525	0.046
		Median	4.285	0.010	4.670	-0.030	4.100	0.050	4.410	0.010
		Min, Max	2.22, 6.43	-0.69, 0.55	2.35, 6.32	-0.55, 0.43	2.59, 6.13	-0.32, 0.46	2.22, 6.43	-0.69, 0.55

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Best measured FVC value (with bronchodilator) (L)	Day 91/Discharge n Ambulatory		74	74	34	34	31	31	139	139
		Mean	4.129	-0.091	4.581	-0.110	4.021	-0.107	4.215	-0.099
		(SD)	(1.0955)	(0.2666)	(0.8041)	(0.2190)	(0.9620)	(0.2004)	(1.0179)	(0.2406)
		95% CI of	3.874,	-0.153,	4.300,	-0.187,	3.668,	-0.181,	4.044,	-0.140,
		Mean	4.383	-0.028	4.862	-0.033	4.374	-0.033	4.387	-0.058
		Median	4.170	-0.070	4.635	-0.115	3.950	-0.090	4.300	-0.080
		Min, Max	2.10, 6.31	-1.12, 0.36	2.27, 6.04	-0.63, 0.38	2.55, 6.19	-0.57, 0.34	2.10, 6.31	-1.12, 0.38

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Percent of predicted FVC value (with bronchodilator) (%)	Baseline	n	79		41		39		159	
		Mean	94.6		99.8		95.2		96.1	
		(SD)	(13.72)		(14.66)		(13.02)		(13.89)	
		95% CI of Mean	91.4, 97.7		95.2, 104.5		91.0, 99.5		93.9, 98.3	
		Median	96.0		98.0		95.0		96.0	
		Min, Max	62, 122		71, 128		64, 125		62, 128	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Percent of predicted FVC value (with bronchodilator) (%)	Day 6/Discharge Confinement	n	78	78	40	40	33	33	151	151
		Mean	94.9	0.3	98.6	-1.6	95.8	1.9	96.1	0.2
		(SD)	(14.19)	(5.30)	(14.44)	(6.39)	(13.48)	(4.48)	(14.10)	(5.55)
		95% CI of Mean	91.7, 98.2	-0.9, 1.6	93.9, 103.2	-3.7, 0.5	91.0, 100.7	0.3, 3.5	93.8, 98.4	-0.8, 1.1
		Median	98.0	1.0	97.5	-1.0	93.0	1.0	97.0	0.0
		Min, Max	65, 126	-20, 15	70, 128	-30, 8	66, 125	-6, 14	65, 128	-30, 15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Percent of predicted FVC value (with bronchodilator) (%)	Day 91/Discharge n Ambulatory		74	74	34	34	31	31	139	139
		Mean	91.5	-2.6	96.7	-2.8	91.3	-2.2	92.7	-2.6
		(SD)	(15.28)	(6.58)	(15.32)	(5.52)	(13.63)	(4.89)	(15.01)	(5.95)
		95% CI of Mean	87.9, 95.1	-4.2, -1.0	91.3, 102.1	-4.7, -0.8	86.2, 96.3	-4.0, -0.3	90.2, 95.3	-3.6, -1.5
		Median	93.0	-1.5	94.5	-2.0	88.0	-2.0	92.0	-2.0
		Min, Max	47, 125	-31, 7	68, 123	-18, 8	59, 119	-14, 8	47, 125	-31, 8

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Best measured FEV1 value (with bronchodilator) (L)	Baseline	n	79		41		39		159	
		Mean	3.386		3.633		3.379		3.448	
		(SD)	(0.8347)		(0.7404)		(0.7953)		(0.8042)	
		95% CI of	3.199,		3.399,		3.121,		3.322,	
		Mean	3.574		3.867		3.638		3.575	
		Median	3.410		3.710		3.520		3.460	
		Min, Max	1.83, 5.18		2.05, 5.10		1.90, 4.85		1.83, 5.18	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Best measured FEV1 value (with bronchodilator) (L)	Day 6/Discharge Confinement	n	78	78	40	40	33	33	151	151
		Mean	3.388	0.008	3.624	-0.048	3.414	0.116	3.456	0.017
		(SD)	(0.8670)	(0.2000)	(0.7062)	(0.2127)	(0.8190)	(0.1894)	(0.8179)	(0.2080)
		95% CI of	3.192,	-0.037,	3.398,	-0.117,	3.123,	0.048,	3.324,	-0.017,
		Mean	3.584	0.054	3.851	0.021	3.705	0.184	3.588	0.051
		Median	3.385	0.030	3.730	-0.070	3.650	0.070	3.510	0.020
		Min, Max	0.96, 5.24	-1.00, 0.42	1.98, 5.10	-0.53, 0.54	2.07, 5.04	-0.20, 0.54	0.96, 5.24	-1.00, 0.54

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Best measured FEV1 value (with bronchodilator) (L)	Day 91/Discharge n Ambulatory	n	74	74	34	34	31	31	139	139
		Mean	3.250	-0.109	3.587	-0.101	3.175	-0.089	3.316	-0.103
		(SD)	(0.8894)	(0.3060)	(0.6673)	(0.2109)	(0.8083)	(0.2903)	(0.8318)	(0.2803)
		95% CI of	3.044,	-0.181,	3.354,	-0.175,	2.878,	-0.196,	3.176,	-0.150,
		Mean	3.457	-0.038	3.821	-0.027	3.472	0.018	3.456	-0.055
		Median	3.205	-0.060	3.740	-0.070	3.070	-0.070	3.340	-0.070
		Min, Max	1.57, 5.25	-1.53, 0.32	2.04, 4.89	-0.60, 0.59	2.07, 5.12	-1.02, 0.48	1.57, 5.25	-1.53, 0.59

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Percent of predicted FEV1 value (with bronchodilator) (%)	Baseline	n	79		41		39		159	
		Mean	93.4		96.3		92.9		94.1	
		(SD)	(12.58)		(13.74)		(12.78)		(12.93)	
		95% CI of Mean	90.6, 96.3		92.0, 100.7		88.7, 97.1		92.0, 96.1	
		Median	94.0		94.0		92.0		94.0	
		Min, Max	60, 122		71, 126		63, 123		60, 126	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Percent of predicted FEV1 value (with bronchodilator) (%)	Day 6/Discharge Confinement	n	78	78	40	40	33	33	151	151
		Mean	93.2	-0.2	95.1	-1.5	95.6	3.2	94.2	0.2
		(SD)	(14.56)	(7.24)	(14.17)	(7.23)	(13.30)	(5.32)	(14.14)	(7.02)
		95% CI of Mean	89.9, 96.5	-1.9, 1.5	90.5, 99.7	-3.8, 0.9	90.8, 100.3	1.2, 5.1	91.9, 96.6	-1.0, 1.4
		Median	96.0	1.0	94.0	-1.0	95.0	3.0	95.0	1.0
		Min, Max	37, 123	-40, 16	66, 126	-26, 17	68, 119	-6, 14	37, 126	-40, 17

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Percent of predicted FEV1 value (with bronchodilator) (%)	Day 91/Discharge n Ambulatory		74	74	34	34	31	31	139	139
		Mean	89.1	-4.2	92.8	-3.5	88.8	-3.1	89.9	-3.8
		(SD)	(15.63)	(9.46)	(14.56)	(6.70)	(12.51)	(8.27)	(14.72)	(8.55)
		95% CI of Mean	85.5, 92.8	-6.5, -2.0	87.7, 97.9	-5.9, -1.1	84.1, 93.4	-6.2, 0.0	87.4, 92.5	-5.3, -2.3
		Median	91.0	-2.0	88.0	-3.0	89.0	-3.0	90.0	-3.0
		Min, Max	45, 119	-42, 9	68, 121	-21, 15	60, 112	-30, 12	45, 121	-42, 15

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Calculated ratio between FEV1/FVC (with bronchodilator) (RATIO)	Baseline	n	79		41		39		159	
		Mean	0.794		0.795		0.794		0.794	
		(SD)	(0.0656)		(0.0555)		(0.0677)		(0.0633)	
		95% CI of	0.779,		0.777,		0.771,		0.784,	
		Mean	0.809		0.813		0.816		0.804	
		Median	0.800		0.800		0.790		0.800	
		Min, Max	0.54, 0.90		0.68, 0.90		0.59, 0.91		0.54, 0.91	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Mid expiratory flow 25-75 (with bronchodilator) (L/s)	Baseline	n	79		41		39		159	
		Mean	3.231		3.344		3.153		3.241	
		(SD)	(1.0885)		(1.0849)		(0.9418)		(1.0493)	
		95% CI of	2.986,		3.001,		2.847,		3.076,	
		Mean	3.475		3.687		3.458		3.406	
		Median	3.210		3.270		3.260		3.230	
		Min, Max	0.96, 6.17		1.50, 5.13		1.47, 4.81		0.96, 6.17	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Mid expiratory flow 25-75 (with bronchodilator) (L/s)	Day 6/Discharge Confinement	n	78	78	40	40	33	33	151	151
		Mean	3.268	0.049	3.380	-0.010	3.302	0.160	3.305	0.057
		(SD)	(1.2364)	(0.6125)	(1.0558)	(0.5288)	(1.0857)	(0.5530)	(1.1525)	(0.5780)
		95% CI of	2.989,	-0.090,	3.042,	-0.180,	2.917,	-0.036,	3.119,	-0.036,
		Mean	3.547	0.187	3.718	0.160	3.688	0.357	3.491	0.151
		Median	3.135	0.035	3.635	-0.025	3.420	0.160	3.260	0.040
		Min, Max	0.54, 6.89	-1.38, 3.28	0.51, 4.97	-1.18, 1.69	1.64, 5.33	-0.85, 1.79	0.51, 6.89	-1.38, 3.28

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Mid expiratory flow 25-75 (with bronchodilator) (L/s)	Day 91/Discharge n Ambulatory	n	73	73	34	34	31	31	138	138
		Mean	4.753	1.491	5.592	2.211	3.073	-0.035	4.582	1.326
		(SD)	(10.5623)	(10.4641)	(13.1844)	(13.0081)	(1.1524)	(0.8060)	(10.0785)	(9.9537)
		95% CI of	2.288,	-0.951,	0.991,	-2.328,	2.650,	-0.331,	2.885,	-0.350,
		Mean	7.218	3.933	10.193	6.750	3.496	0.261	6.279	3.002
		Median	3.060	-0.110	3.395	0.005	2.840	-0.120	3.105	-0.080
		Min, Max	0.26, 84.00	-3.76, 79.88	1.65, 80.00	-1.93, 75.76	1.53, 6.09	-1.53, 3.22	0.26, 84.00	-3.76, 79.88

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Ratio between FEV1/FVC (Derived) (RATIO)	Baseline	n	78		40		35		153	
		Mean	0.796		0.787		0.792		0.793	
		(SD)	(0.0538)		(0.0647)		(0.0522)		(0.0562)	
		95% CI of	0.783,		0.766,		0.773,		0.783,	
		Mean	0.809		0.808		0.810		0.802	
		Median	0.800		0.785		0.790		0.790	
		Min, Max	0.66, 0.90		0.61, 0.91		0.68, 0.95		0.61, 0.95	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Ratio between FEV1/FVC (Derived) (RATIO)	Day 6/Discharge Confinement	n	78	78	40	40	33	33	151	151
		Mean	0.791	-0.005	0.784	-0.003	0.804	0.013	0.792	0.000
		(SD)	(0.0701)	(0.0476)	(0.0747)	(0.0327)	(0.0507)	(0.0314)	(0.0676)	(0.0412)
		95% CI of	0.775,	-0.016,	0.760,	-0.014,	0.786,	0.001,	0.781,	-0.008,
		Mean	0.807	0.006	0.809	0.008	0.823	0.024	0.804	0.007
		Median	0.800	0.000	0.795	0.000	0.810	0.010	0.800	0.000
		Min, Max	0.43, 0.90	-0.37, 0.04	0.53, 0.90	-0.08, 0.09	0.70, 0.94	-0.04, 0.12	0.43, 0.94	-0.37, 0.12

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Ratio between FEV1/FVC (Derived) (RATIO)	Day 91/Discharge n Ambulatory		74	74	34	34	31	31	139	139
		Mean	0.789	-0.010	0.785	-0.003	0.791	0.000	0.788	-0.006
		(SD)	(0.0657)	(0.0386)	(0.0663)	(0.0342)	(0.0666)	(0.0485)	(0.0656)	(0.0400)
		95% CI of	0.773,	-0.020,	0.761,	-0.015,	0.766,	-0.018,	0.777,	-0.013,
		Mean	0.805	-0.001	0.809	0.010	0.816	0.019	0.800	0.001
		Median	0.800	0.000	0.790	0.000	0.800	0.000	0.800	0.000
		Min, Max	0.48, 0.90	-0.19, 0.06	0.65, 0.90	-0.11, 0.06	0.58, 0.91	-0.15, 0.13	0.48, 0.91	-0.19, 0.13

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Diffusion Capacity Baseline for Lung CO (mL/min/mmHg)	Baseline	n	76		40		33		149	
		Mean	23.290		24.379		23.118		23.545	
		(SD)	(5.9644)		(6.2093)		(6.1601)		(6.0543)	
		95% CI of	21.927,		22.393,		20.934,		22.564,	
		Mean	24.654		26.366		25.303		24.525	
		Median	23.600		24.235		24.420		24.010	
		Min, Max	12.79, 36.66		12.20, 46.10		11.41, 32.94		11.41, 46.10	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Diffusion Capacity for Lung CO (mL/min/mmHg)	Day 6/Discharge Confinement	n	77	75	40	40	33	31	150	146
		Mean	23.453	0.171	23.567	-0.813	23.005	0.008	23.385	-0.133
		(SD)	(6.0903)	(2.0087)	(5.8598)	(2.4153)	(6.0305)	(2.3273)	(5.9800)	(2.2200)
		95% CI of	22.070,	-0.291,	21.692,	-1.585,	20.866,	-0.846,	22.419,	-0.496,
		Mean	24.836	0.634	25.441	-0.040	25.143	0.863	24.350	0.231
		Median	22.700	0.200	24.290	-0.755	23.410	0.020	23.125	0.065
		Min, Max	12.36,	-5.77, 4.64	12.98,	-7.89, 4.51	12.31,	-4.90, 5.10	12.31,	-7.89, 5.10
			40.14		42.99		34.21		42.99	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Diffusion Capacity for Lung CO (mL/min/mmHg)	Day 91/Discharge n Ambulatory		71	70	34	34	31	29	136	133
		Mean	23.323	0.470	24.994	-0.019	22.558	-0.034	23.566	0.235
		(SD)	(5.7459)	(2.3818)	(6.7262)	(3.1707)	(6.3449)	(3.1106)	(6.1565)	(2.7556)
		95% CI of	21.962,	-0.098,	22.646,	-1.126,	20.230,	-1.217,	22.522,	-0.238,
		Mean	24.683	1.039	27.341	1.087	24.886	1.150	24.611	0.708
		Median	23.320	0.725	23.950	-0.475	22.330	0.130	23.320	0.600
		Min, Max	11.20,	-5.35, 7.00	13.94,	-5.09, 6.77	11.49,	-8.28, 6.35	11.20,	-8.28, 7.00
			38.74		42.01		35.38		42.01	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Rate Constant of CO (mmol/min/kPa/L)	Baseline	n	76		40		33		149	
		Mean	1.376		1.344		1.325		1.356	
		(SD)	(0.2680)		(0.2527)		(0.2667)		(0.2628)	
		95% CI of	1.314,		1.263,		1.230,		1.313,	
		Mean	1.437		1.425		1.420		1.399	
		Median	1.355		1.290		1.320		1.340	
		Min, Max	0.75, 2.01		0.93, 1.95		0.79, 2.05		0.75, 2.05	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Rate Constant of CO (mmol/min/kPa/L)	Day 6/Discharge Confinement	n	77	75	40	40	33	31	150	146
		Mean	1.373	-0.001	1.322	-0.023	1.326	-0.022	1.349	-0.011
		(SD)	(0.2605)	(0.1036)	(0.2647)	(0.1235)	(0.2751)	(0.1294)	(0.2642)	(0.1147)
		95% CI of	1.313,	-0.025,	1.236,	-0.062,	1.228,	-0.070,	1.306,	-0.031,
		Mean	1.432	0.023	1.407	0.017	1.424	0.026	1.392	0.008
		Median	1.380	-0.010	1.355	-0.010	1.350	-0.030	1.370	-0.010
		Min, Max	0.75, 2.05	-0.23, 0.32	0.72, 1.80	-0.26, 0.24	0.81, 1.93	-0.29, 0.25	0.72, 2.05	-0.29, 0.32

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Rate Constant of CO (mmol/min/kPa/L)	Day 91/Discharge n Ambulatory		71	70	34	34	30	28	135	132
		Mean	1.408	0.040	1.346	-0.021	1.327	0.013	1.375	0.019
		(SD)	(0.3119)	(0.1380)	(0.2597)	(0.1346)	(0.3003)	(0.1686)	(0.2971)	(0.1453)
		95% CI of	1.334,	0.007,	1.255,	-0.069,	1.215,	-0.053,	1.324,	-0.007,
		Mean	1.483	0.074	1.438	0.026	1.440	0.079	1.426	0.044
		Median	1.380	0.020	1.400	-0.020	1.330	0.015	1.380	0.000
		Min, Max	0.71, 2.41	-0.23, 0.53	0.83, 2.02	-0.29, 0.27	0.81, 2.00	-0.38, 0.29	0.71, 2.41	-0.38, 0.53

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Inspiratory Capacity (L)	Baseline	n	78		40		35		153	
		Mean	2.861		2.984		2.957		2.915	
		(SD)	(0.9661)		(0.8578)		(0.9802)		(0.9379)	
		95% CI of	2.643,		2.709,		2.620,		2.765,	
		Mean	3.079		3.259		3.294		3.065	
		Median	2.820		2.955		2.820		2.850	
		Min, Max	0.49, 5.90		0.48, 4.33		0.94, 5.04		0.48, 5.90	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Inspiratory Capacity (L)	Day 6/Discharge Confinement	n	78	78	40	40	33	33	151	151
		Mean	3.088	0.227	3.062	0.078	2.968	0.042	3.055	0.147
		(SD)	(0.8996)	(0.6062)	(0.6070)	(0.6343)	(0.9020)	(0.6948)	(0.8288)	(0.6350)
		95% CI of	2.885,	0.090,	2.867,	-0.125,	2.648,	-0.205,	2.921,	0.044, 0.250
		Mean	3.291	0.364	3.257	0.281	3.289	0.288	3.189	
		Median	2.970	0.225	3.165	-0.040	2.900	0.080	3.020	0.100
		Min, Max	0.60, 5.45	-2.18, 2.12	1.49, 4.17	-1.00, 2.73	0.99, 5.12	-2.31, 2.14	0.60, 5.45	-2.31, 2.73

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Inspiratory Capacity (L)	Day 91/Discharge n Ambulatory		74	74	34	34	31	31	139	139
		Mean	2.989	0.190	2.987	-0.071	2.769	-0.141	2.939	0.052
		(SD)	(1.0840)	(0.7240)	(0.8131)	(0.6457)	(0.9838)	(0.8953)	(0.9992)	(0.7573)
		95% CI of	2.737,	0.022,	2.703,	-0.296,	2.408,	-0.470,	2.771,	-0.075,
		Mean	3.240	0.358	3.272	0.155	3.130	0.188	3.107	0.180
		Median	2.975	0.160	2.965	-0.025	2.700	0.030	2.850	0.070
		Min, Max	0.49, 7.36	-1.16, 4.32	1.10, 4.51	-2.19, 1.56	0.77, 4.99	-3.53, 1.76	0.49, 7.36	-3.53, 4.32

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Residual Volume (L)	Baseline	n	78		40		35		153	
		Mean	3.083		3.158		2.951		3.073	
		(SD)	(1.2369)		(0.9214)		(0.6550)		(1.0460)	
		95% CI of	2.804,		2.863,		2.726,		2.905,	
		Mean	3.363		3.453		3.177		3.240	
		Median	2.830		3.240		3.030		3.010	
		Min, Max	1.41, 8.77		1.72, 6.04		1.24, 4.38		1.24, 8.77	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Residual Volume (L)	Day 6/Discharge Confinement	n	78	78	40	40	33	33	151	151
		Mean	2.919	-0.164	3.165	0.007	3.097	0.153	3.023	-0.050
		(SD)	(0.9839)	(1.1674)	(0.9927)	(0.8044)	(1.7552)	(1.7874)	(1.1927)	(1.2515)
		95% CI of	2.697,	-0.428,	2.847,	-0.251,	2.474,	-0.482,	2.831,	-0.252,
		Mean	3.141	0.099	3.483	0.264	3.720	0.787	3.215	0.152
		Median	2.830	-0.060	3.140	-0.030	2.800	-0.140	2.960	-0.050
		Min, Max	1.24, 8.19	-6.40, 4.81	1.57, 7.28	-2.99, 3.01	1.50, 12.15	-1.34, 9.76	1.24, 12.15	-6.40, 9.76

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Residual Volume (L)	Day 91/Discharge n Ambulatory		74	74	34	34	31	31	139	139
		Mean	2.801	-0.285	3.031	-0.171	2.823	-0.124	2.862	-0.221
		(SD)	(0.7122)	(1.0871)	(0.8343)	(0.7192)	(0.6331)	(0.5823)	(0.7289)	(0.9097)
		95% CI of	2.635,	-0.538,	2.739,	-0.422,	2.590,	-0.338,	2.739,	-0.374,
		Mean	2.966	-0.033	3.322	0.081	3.056	0.091	2.985	-0.068
		Median	2.685	-0.095	3.015	-0.105	2.880	-0.150	2.850	-0.100
		Min, Max	1.30, 5.06	-6.54, 1.04	1.80, 5.55	-2.89, 1.61	1.57, 4.26	-1.21, 1.87	1.30, 5.55	-6.54, 1.87

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Total Lung Capacity (L)	Baseline	n	78		40		35		153	
		Mean	5.944		6.142		5.908		5.988	
		(SD)	(1.7602)		(1.1831)		(1.3833)		(1.5380)	
		95% CI of	5.547,		5.763,		5.433,		5.742,	
		Mean	6.342		6.521		6.384		6.234	
		Median	5.915		6.195		5.800		5.880	
		Min, Max	2.74, 13.07		3.19, 8.92		2.46, 8.94		2.46, 13.07	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Total Lung Capacity (L)	Day 6/Discharge Confinement	n	78	78	40	40	33	33	151	151
		Mean	6.007	0.062	6.227	0.085	6.066	0.194	6.078	0.097
		(SD)	(1.4464)	(1.2483)	(1.2502)	(1.1067)	(1.8106)	(1.9461)	(1.4793)	(1.3889)
		95% CI of	5.680,	-0.220,	5.826,	-0.270,	5.423,	-0.496,	5.840,	-0.127,
		Mean	6.334	0.344	6.627	0.439	6.708	0.885	6.316	0.321
		Median	5.980	0.140	6.245	-0.025	5.750	-0.070	6.040	0.030
		Min, Max	2.35, 11.02	-5.98, 4.72	3.22, 10.49	-2.16, 5.74	3.67, 13.90	-3.41, 9.67	2.35, 13.90	-5.98, 9.67

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Total Lung Capacity (L)	Day 91/Discharge n Ambulatory		74	74	34	34	31	31	139	139
		Mean	5.789	-0.095	6.018	-0.241	5.592	-0.265	5.801	-0.169
		(SD)	(1.4257)	(1.2944)	(1.1739)	(0.8871)	(1.1844)	(1.1178)	(1.3158)	(1.1629)
		95% CI of	5.458,	-0.396,	5.608,	-0.551,	5.157,	-0.675,	5.580,	-0.364,
		Mean	6.120	0.205	6.428	0.069	6.027	0.146	6.022	0.027
		Median	5.905	0.060	6.095	-0.125	5.400	-0.170	5.840	-0.020
		Min, Max	2.78, 9.02	-7.09, 3.49	3.05, 9.03	-2.56, 2.08	3.57, 8.17	-4.49, 1.83	2.78, 9.03	-7.09, 3.49

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Vital Capacity (L)	Baseline	n	78		40		35		153	
		Mean	4.335		4.732		4.272		4.424	
		(SD)	(1.0543)		(0.8614)		(1.0123)		(1.0085)	
		95% CI of	4.097,		4.456,		3.924,		4.263,	
		Mean	4.573		5.008		4.620		4.586	
		Median	4.360		4.810		4.310		4.450	
		Min, Max	2.37, 6.44		2.39, 6.35		2.45, 6.39		2.37, 6.44	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Vital Capacity (L)	Day 6/Discharge Confinement	n	78	78	40	40	33	33	151	151
		Mean	4.385	0.051	4.679	-0.053	4.299	0.081	4.444	0.030
		(SD)	(1.0417)	(0.1933)	(0.8379)	(0.1747)	(0.9839)	(0.2684)	(0.9835)	(0.2124)
		95% CI of	4.150,	0.007,	4.411,	-0.109,	3.950,	-0.014,	4.286,	-0.005,
		Mean	4.621	0.095	4.948	0.004	4.648	0.177	4.603	0.065
		Median	4.325	0.020	4.765	-0.040	4.240	0.100	4.480	0.020
		Min, Max	2.31, 6.43	-0.31, 0.79	2.35, 6.38	-0.54, 0.26	2.62, 6.20	-0.81, 0.57	2.31, 6.43	-0.81, 0.79

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.22 Summary of Full Lung Function Results - Safety Population****Safety Time Period: Randomization Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Vital Capacity (L)	Day 91/Discharge n Ambulatory		73	73	34	34	31	31	138	138
		Mean	4.277	-0.021	4.584	-0.170	4.096	-0.087	4.312	-0.073
		(SD)	(1.1537)	(0.4341)	(0.8288)	(0.1846)	(1.0060)	(0.2423)	(1.0565)	(0.3520)
		95% CI of	4.007,	-0.123,	4.295,	-0.235,	3.727,	-0.177,	4.134,	-0.132,
		Mean	4.546	0.080	4.874	-0.105	4.466	0.002	4.490	-0.013
		Median	4.240	-0.060	4.655	-0.180	3.950	-0.080	4.380	-0.095
		Min, Max	2.36, 7.82	-0.49, 3.27	2.24, 6.24	-0.61, 0.17	2.60, 6.28	-0.91, 0.42	2.24, 7.82	-0.91, 3.27

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THS = Tobacco Heating System.

Note: NCS = not clinically significant; CS = clinically significant. Note: Change is change from baseline, where baseline is the last assessment prior to first product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 08:00 AM in SA arm on Day 1.

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Head, Eyes, Ears, Nose, Throat	Baseline	Normal - n (%)	69 (86.3)	35 (85.4)	37 (94.9)	141 (88.1)
		Abnormal NCS - n (%)	10 (12.5)	6 (14.6)	2 (5.1)	18 (11.3)
	Day 6/Discharge Confinement	Normal - n (%)	70 (87.5)	35 (85.4)	33 (84.6)	138 (86.3)
		Normal to Normal - n (%)	69 (86.3)	34 (82.9)	33 (84.6)	136 (85.0)
		Abnormal NCS to Normal - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Abnormal NCS - n (%)	9 (11.3)	5 (12.2)	2 (5.1)	16 (10.0)
		Abnormal NCS to Abnormal NCS - n (%)	9 (11.3)	5 (12.2)	2 (5.1)	16 (10.0)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Head, Eyes, Ears, Nose, Throat	Day 30	Normal - n (%)	68 (85.0)	34 (82.9)	30 (76.9)	132 (82.5)
		Normal to Normal - n (%)	67 (83.8)	34 (82.9)	30 (76.9)	131 (81.9)
		Abnormal NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS - n (%)	9 (11.3)	5 (12.2)	2 (5.1)	16 (10.0)
		Normal to Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS to Abnormal NCS - n (%)	8 (10.0)	5 (12.2)	2 (5.1)	15 (9.4)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Head, Eyes, Ears, Nose, Throat	Day 60	Normal - n (%)	64 (80.0)	30 (73.2)	28 (71.8)	122 (76.3)
		Normal to Normal - n (%)	62 (77.5)	30 (73.2)	28 (71.8)	120 (75.0)
		Abnormal NCS to Normal - n (%)	2 (2.5)	0	0	2 (1.3)
		Abnormal NCS - n (%)	8 (10.0)	6 (14.6)	2 (5.1)	16 (10.0)
		Normal to Abnormal NCS - n (%)	2 (2.5)	0	0	2 (1.3)
		Abnormal NCS to Abnormal NCS - n (%)	6 (7.5)	6 (14.6)	2 (5.1)	14 (8.8)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Head, Eyes, Ears, Nose, Throat	Day 91/Discharge Ambulatory	Normal - n (%)	65 (81.3)	30 (73.2)	30 (76.9)	125 (78.1)
		Normal to Normal - n (%)	64 (80.0)	30 (73.2)	30 (76.9)	124 (77.5)
		Abnormal NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS - n (%)	9 (11.3)	5 (12.2)	3 (7.7)	17 (10.6)
		Normal to Abnormal NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		Abnormal NCS to Abnormal NCS - n (%)	8 (10.0)	5 (12.2)	2 (5.1)	15 (9.4)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Thyroid Gland	Baseline	Normal - n (%)	79 (98.8)	41 (100)	39 (100)	159 (99.4)
		Normal to Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
			79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
	Day 6/Discharge Confinement	Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		Normal to Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
	Day 30	Normal - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)
		Normal to Normal - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)
	Day 60	Normal - n (%)	72 (90.0)	36 (87.8)	30 (76.9)	138 (86.3)
		Normal to Normal - n (%)	72 (90.0)	36 (87.8)	30 (76.9)	138 (86.3)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Thyroid Gland	Day 91/Discharge Ambulatory	Normal - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)
		Normal to Normal - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)
Heart	Baseline	Normal - n (%)	79 (98.8)	41 (100)	39 (100)	159 (99.4)
		Normal to Normal - n (%)	79 (98.8)	41 (100)	39 (100)	159 (99.4)
	Day 6/Discharge Confinement	Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		Normal to Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
	Day 30	Normal - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)
		Normal to Normal - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Heart	Day 60	Normal - n (%)	72 (90.0)	36 (87.8)	30 (76.9)	138 (86.3)
		Normal to Normal - n (%)	72 (90.0)	36 (87.8)	30 (76.9)	138 (86.3)
	Day 91/Discharge Ambulatory	Normal - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)
		Normal to Normal - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)
Chest	Baseline	Normal - n (%)	79 (98.8)	41 (100)	39 (100)	159 (99.4)
	Day 6/Discharge Confinement	Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		Normal to Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Chest	Day 30	Normal - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)
		Normal to Normal - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)
	Day 60	Normal - n (%)	72 (90.0)	36 (87.8)	30 (76.9)	138 (86.3)
		Normal to Normal - n (%)	72 (90.0)	36 (87.8)	30 (76.9)	138 (86.3)
	Day 91/Discharge Ambulatory	Normal - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)
		Normal to Normal - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Lungs	Baseline	Normal - n (%)	78 (97.5)	41 (100)	39 (100)	158 (98.8)
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)
	Day 6/Discharge Confinement	Normal - n (%)	78 (97.5)	40 (97.6)	35 (89.7)	153 (95.6)
		Normal to Normal - n (%)	78 (97.5)	40 (97.6)	35 (89.7)	153 (95.6)
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS to Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Lungs	Day 30	Normal - n (%)	76 (95.0)	39 (95.1)	32 (82.1)	147 (91.9)
		Normal to Normal - n (%)	76 (95.0)	39 (95.1)	32 (82.1)	147 (91.9)
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS to Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)
	Day 60	Normal - n (%)	71 (88.8)	36 (87.8)	30 (76.9)	137 (85.6)
		Normal to Normal - n (%)	71 (88.8)	36 (87.8)	30 (76.9)	137 (85.6)
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS to Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Lungs	Day 91/Discharge Ambulatory	Normal - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)
		Normal to Normal - n (%)	73 (91.3)	35 (85.4)	33 (84.6)	141 (88.1)
		Abnormal NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
Gastrointestinal	Baseline	Normal - n (%)	79 (98.8)	41 (100)	39 (100)	159 (99.4)
		Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		Normal to Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Gastrointestinal	Day 30	Normal - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)
		Normal to Normal - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)
	Day 60	Normal - n (%)	72 (90.0)	36 (87.8)	30 (76.9)	138 (86.3)
		Normal to Normal - n (%)	72 (90.0)	36 (87.8)	30 (76.9)	138 (86.3)
	Day 91/Discharge Ambulatory	Normal - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)
		Normal to Normal - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Cardiovascular System	Baseline	Normal - n (%)	78 (97.5)	41 (100)	39 (100)	158 (98.8)
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)
	Day 6/Discharge Confinement	Normal - n (%)	78 (97.5)	40 (97.6)	35 (89.7)	153 (95.6)
		Normal to Normal - n (%)	78 (97.5)	40 (97.6)	35 (89.7)	153 (95.6)
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS to Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Cardiovascular System	Day 30	Normal - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)
		Normal to Normal - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)
	Day 60	Normal - n (%)	71 (88.8)	36 (87.8)	30 (76.9)	137 (85.6)
		Normal to Normal - n (%)	71 (88.8)	36 (87.8)	30 (76.9)	137 (85.6)
		Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS to Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Cardiovascular System	Day 91/Discharge Ambulatory	Normal - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)
		Normal to Normal - n (%)	73 (91.3)	35 (85.4)	33 (84.6)	141 (88.1)
		Abnormal NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
Neurologic	Baseline	Normal - n (%)	79 (98.8)	41 (100)	37 (94.9)	157 (98.1)
		Abnormal NCS - n (%)	0	0	2 (5.1)	2 (1.3)
	Day 6/Discharge Confinement	Normal - n (%)	79 (98.8)	40 (97.6)	33 (84.6)	152 (95.0)
		Normal to Normal - n (%)	79 (98.8)	40 (97.6)	33 (84.6)	152 (95.0)
		Abnormal NCS - n (%)	0	0	2 (5.1)	2 (1.3)
		Abnormal NCS to Abnormal NCS - n (%)	0	0	2 (5.1)	2 (1.3)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Neurologic	Day 30	Normal - n (%)	77 (96.3)	39 (95.1)	31 (79.5)	147 (91.9)
		Normal to Normal - n (%)	77 (96.3)	39 (95.1)	31 (79.5)	147 (91.9)
		Abnormal NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		Abnormal NCS to Abnormal NCS - n (%)	0	0	1 (2.6)	1 (0.6)
	Day 60	Normal - n (%)	72 (90.0)	36 (87.8)	29 (74.4)	137 (85.6)
		Normal to Normal - n (%)	72 (90.0)	36 (87.8)	29 (74.4)	137 (85.6)
		Abnormal NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		Abnormal NCS to Abnormal NCS - n (%)	0	0	1 (2.6)	1 (0.6)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Neurologic	Day 91/Discharge Ambulatory	Normal - n (%)	74 (92.5)	35 (85.4)	32 (82.1)	141 (88.1)
		Normal to Normal - n (%)	74 (92.5)	35 (85.4)	32 (82.1)	141 (88.1)
		Abnormal NCS - n (%)	0	0	1 (2.6)	1 (0.6)
		Abnormal NCS to Abnormal NCS - n (%)	0	0	1 (2.6)	1 (0.6)
Skin	Baseline	Normal - n (%)	72 (90.0)	38 (92.7)	37 (94.9)	147 (91.9)
		Abnormal NCS - n (%)	7 (8.8)	3 (7.3)	2 (5.1)	12 (7.5)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Skin	Day 6/Discharge Confinement	Normal - n (%)	75 (93.8)	33 (80.5)	33 (84.6)	141 (88.1)
		Normal to Normal - n (%)	72 (90.0)	33 (80.5)	33 (84.6)	138 (86.3)
		Abnormal NCS to Normal - n (%)	3 (3.8)	0	0	3 (1.9)
		Abnormal NCS - n (%)	4 (5.0)	7 (17.1)	2 (5.1)	13 (8.1)
		Normal to Abnormal NCS - n (%)	0	4 (9.8)	0	4 (2.5)
		Abnormal NCS to Abnormal NCS - n (%)	4 (5.0)	3 (7.3)	2 (5.1)	9 (5.6)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Skin	Day 30	Normal - n (%)	70 (87.5)	33 (80.5)	31 (79.5)	134 (83.8)
		Normal to Normal - n (%)	67 (83.8)	32 (78.0)	31 (79.5)	130 (81.3)
		Abnormal NCS to Normal - n (%)	3 (3.8)	1 (2.4)	0	4 (2.5)
		Abnormal NCS - n (%)	7 (8.8)	6 (14.6)	1 (2.6)	14 (8.8)
		Normal to Abnormal NCS - n (%)	3 (3.8)	4 (9.8)	0	7 (4.4)
		Abnormal NCS to Abnormal NCS - n (%)	4 (5.0)	2 (4.9)	1 (2.6)	7 (4.4)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Skin	Day 60	Normal - n (%)	64 (80.0)	31 (75.6)	28 (71.8)	123 (76.9)
		Normal to Normal - n (%)	61 (76.3)	31 (75.6)	28 (71.8)	120 (75.0)
		Abnormal NCS to Normal - n (%)	3 (3.8)	0	0	3 (1.9)
		Abnormal NCS - n (%)	8 (10.0)	5 (12.2)	2 (5.1)	15 (9.4)
		Normal to Abnormal NCS - n (%)	4 (5.0)	2 (4.9)	0	6 (3.8)
		Abnormal NCS to Abnormal NCS - n (%)	4 (5.0)	3 (7.3)	2 (5.1)	9 (5.6)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Skin	Day 91/Discharge Ambulatory	Normal - n (%)	67 (83.8)	30 (73.2)	31 (79.5)	128 (80.0)
		Normal to Normal - n (%)	64 (80.0)	30 (73.2)	31 (79.5)	125 (78.1)
		Abnormal NCS to Normal - n (%)	3 (3.8)	0	0	3 (1.9)
		Abnormal NCS - n (%)	7 (8.8)	5 (12.2)	2 (5.1)	14 (8.8)
		Normal to Abnormal NCS - n (%)	3 (3.8)	2 (4.9)	0	5 (3.1)
		Abnormal NCS to Abnormal NCS - n (%)	4 (5.0)	3 (7.3)	2 (5.1)	9 (5.6)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Back	Baseline	Normal - n (%)	79 (98.8)	41 (100)	39 (100)	159 (99.4)
	Day 6/Discharge Confinement	Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		Normal to Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
	Day 30	Normal - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)
		Normal to Normal - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)
	Day 60	Normal - n (%)	72 (90.0)	36 (87.8)	30 (76.9)	138 (86.3)
		Normal to Normal - n (%)	72 (90.0)	36 (87.8)	30 (76.9)	138 (86.3)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Back	Day 91/Discharge Ambulatory	Normal - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)
		Normal to Normal - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)
Musculoskeletal	Baseline	Normal - n (%)	77 (96.3)	38 (92.7)	38 (97.4)	153 (95.6)
		Abnormal NCS - n (%)	2 (2.5)	3 (7.3)	1 (2.6)	6 (3.8)
	Day 6/Discharge Confinement	Normal - n (%)	76 (95.0)	38 (92.7)	34 (87.2)	148 (92.5)
		Normal to Normal - n (%)	76 (95.0)	37 (90.2)	34 (87.2)	147 (91.9)
		Abnormal NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal NCS - n (%)	3 (3.8)	2 (4.9)	1 (2.6)	6 (3.8)
		Normal to Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS to Abnormal NCS - n (%)	2 (2.5)	2 (4.9)	1 (2.6)	5 (3.1)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall Safety
			(N=80)	(N=41)	(N=39)	(N=160)
Musculoskeletal	Day 30	Normal - n (%)	75 (93.8)	38 (92.7)	32 (82.1)	145 (90.6)
		Normal to Normal - n (%)	75 (93.8)	37 (90.2)	32 (82.1)	144 (90.0)
		Abnormal NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal NCS - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		Abnormal NCS to Abnormal NCS - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
	Day 60	Normal - n (%)	70 (87.5)	35 (85.4)	30 (76.9)	135 (84.4)
		Normal to Normal - n (%)	69 (86.3)	34 (82.9)	30 (76.9)	133 (83.1)
		Abnormal NCS to Normal - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)
		Abnormal NCS - n (%)	2 (2.5)	1 (2.4)	0	3 (1.9)
		Normal to Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS to Abnormal NCS - n (%)	1 (1.3)	1 (2.4)	0	2 (1.3)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Musculoskeletal	Day 91/Discharge Ambulatory	Normal - n (%)	71 (88.8)	35 (85.4)	33 (84.6)	139 (86.9)
		Normal to Normal - n (%)	71 (88.8)	34 (82.9)	33 (84.6)	138 (86.3)
		Abnormal NCS to Normal - n (%)	0	1 (2.4)	0	1 (0.6)
		Abnormal NCS - n (%)	3 (3.8)	0	0	3 (1.9)
		Normal to Abnormal NCS - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS to Abnormal NCS - n (%)	2 (2.5)	0	0	2 (1.3)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Abdomen	Baseline	Normal - n (%)	79 (98.8)	41 (100)	39 (100)	159 (99.4)
		Normal to Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		Normal to Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
	Day 6/Discharge Confinement	Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
		Normal to Normal - n (%)	79 (98.8)	40 (97.6)	35 (89.7)	154 (96.3)
	Day 30	Normal - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)
		Normal to Normal - n (%)	77 (96.3)	39 (95.1)	32 (82.1)	148 (92.5)
	Day 60	Normal - n (%)	72 (90.0)	36 (87.8)	30 (76.9)	138 (86.3)
		Normal to Normal - n (%)	72 (90.0)	36 (87.8)	30 (76.9)	138 (86.3)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Abdomen	Day 91/Discharge Ambulatory	Normal - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)
		Normal to Normal - n (%)	74 (92.5)	35 (85.4)	33 (84.6)	142 (88.8)
Dentition	Baseline	Normal - n (%)	63 (78.8)	36 (87.8)	29 (74.4)	128 (80.0)
		Abnormal NCS - n (%)	16 (20.0)	5 (12.2)	10 (25.6)	31 (19.4)
	Day 6/Discharge Confinement	Normal - n (%)	63 (78.8)	35 (85.4)	29 (74.4)	127 (79.4)
		Normal to Normal - n (%)	63 (78.8)	35 (85.4)	27 (69.2)	125 (78.1)
		Abnormal NCS to Normal - n (%)	0	0	2 (5.1)	2 (1.3)
		Abnormal NCS - n (%)	16 (20.0)	5 (12.2)	6 (15.4)	27 (16.9)
		Abnormal NCS to Abnormal NCS - n (%)	16 (20.0)	5 (12.2)	6 (15.4)	27 (16.9)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Dentition	Day 30	Normal - n (%)	61 (76.3)	34 (82.9)	24 (61.5)	119 (74.4)
		Normal to Normal - n (%)	60 (75.0)	34 (82.9)	24 (61.5)	118 (73.8)
		Abnormal NCS to Normal - n (%)	1 (1.3)	0	0	1 (0.6)
		Abnormal NCS - n (%)	16 (20.0)	5 (12.2)	8 (20.5)	29 (18.1)
		Normal to Abnormal NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		Abnormal NCS to Abnormal NCS - n (%)	15 (18.8)	5 (12.2)	7 (17.9)	27 (16.9)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Dentition	Day 60	Normal - n (%)	58 (72.5)	32 (78.0)	22 (56.4)	112 (70.0)
		Normal to Normal - n (%)	56 (70.0)	32 (78.0)	22 (56.4)	110 (68.8)
		Abnormal NCS to Normal - n (%)	2 (2.5)	0	0	2 (1.3)
		Abnormal NCS - n (%)	14 (17.5)	4 (9.8)	8 (20.5)	26 (16.3)
		Normal to Abnormal NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		Abnormal NCS to Abnormal NCS - n (%)	13 (16.3)	4 (9.8)	7 (17.9)	24 (15.0)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.23 Summary of Physical Examination of Body Systems - Safety Population****Safety Time Period: Randomized Period**

Body System	Study Day	Statistic	THSm2.2	mCC	SA	Overall
			(N=80)	(N=41)	(N=39)	Safety (N=160)
Dentition	Day 91/Discharge Ambulatory	Normal - n (%)	61 (76.3)	31 (75.6)	25 (64.1)	117 (73.1)
		Normal to Normal - n (%)	59 (73.8)	31 (75.6)	25 (64.1)	115 (71.9)
		Abnormal NCS to Normal - n (%)	2 (2.5)	0	0	2 (1.3)
		Abnormal NCS - n (%)	13 (16.3)	4 (9.8)	8 (20.5)	25 (15.6)
		Normal to Abnormal NCS - n (%)	1 (1.3)	0	1 (2.6)	2 (1.3)
		Abnormal NCS to Abnormal NCS - n (%)	12 (15.0)	4 (9.8)	7 (17.9)	23 (14.4)

Note: mCC = Menthol Conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol; NCS = not clinically significant; CS = Clinically Significant.

Note: Percentages are based on the number of subjects indicated in the column header (N).

**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Weight (kg)	Baseline	n	79		41		39		159	
		Mean	78.92		75.59		76.52		77.47	
		(SD)	(13.893)		(12.710)		(13.682)		(13.542)	
		Median	78.60		73.70		74.70		76.50	
		Min, Max	52.9, 115.3		49.3, 103.2		48.1, 121.2		48.1, 121.2	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Weight (kg)	Day 6/Discharge Confinement	n	79	79	40	40	35	35	154	154
		Mean	78.18	-0.74	75.15	-0.60	75.60	-0.94	76.80	-0.75
		(SD)	(13.619)	(1.258)	(12.388)	(0.927)	(13.478)	(1.727)	(13.269)	(1.305)
		Median	76.70	-0.70	74.55	-0.65	74.40	-0.80	75.40	-0.70
		Min, Max	53.4, 112.9	-5.0, 2.9	49.1, 101.9	-2.7, 1.0	48.3, 114.6	-6.6, 1.3	48.3, 114.6	-6.6, 2.9

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Weight (kg)	Day 30	n	77	77	39	39	33	33	149	149
		Mean	79.85	0.82	76.62	0.62	76.62	0.76	78.29	0.75
		(SD)	(14.310)	(1.631)	(13.156)	(1.292)	(13.170)	(2.204)	(13.774)	(1.689)
		Median	79.10	0.80	75.80	0.70	73.60	0.60	77.00	0.70
		Min, Max	53.6, 117.3	-3.7, 4.9	51.0, 104.8	-2.0, 2.9	48.4, 115.7	-5.5, 6.6	48.4, 117.3	-5.5, 6.6

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Weight (kg)	Day 60	n	74	74	37	37	31	31	142	142
		Mean	78.97	0.79	77.59	1.02	76.12	0.89	77.99	0.87
		(SD)	(14.120)	(2.323)	(12.989)	(1.699)	(13.063)	(2.251)	(13.562)	(2.149)
		Median	78.15	0.60	77.60	0.90	72.80	0.90	76.95	0.80
		Min, Max	55.2, 117.8	-6.9, 5.8	51.7, 103.2	-2.3, 4.5	50.2, 118.0	-3.2, 5.8	50.2, 118.0	-6.9, 5.8

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change value	Raw value	Change value	Raw value	Change value	Raw value	Change
Weight (kg)	Day 91/Discharge n Ambulatory		79	79	41	40	39	35	159	154
		Mean	79.15	0.24	76.34	0.78	77.06	0.60	77.92	0.46
		(SD)	(13.938)	(2.943)	(13.206)	(2.064)	(13.037)	(2.822)	(13.510)	(2.707)
		Median	77.90	0.70	75.90	0.80	74.90	0.70	76.70	0.70
		Min, Max	54.9, 118.6	-8.6, 7.3	50.7, 104.3	-2.8, 8.1	49.7, 117.4	-5.0, 7.0	49.7, 118.6	-8.6, 8.1

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change value	Raw value	Change value	Raw value	Change value	Raw value	Change
Body Mass Index (kg/m ²)	Baseline	n	79		41		39		159	
		Mean	27.04		25.75		26.20		26.50	
		(SD)	(4.105)		(3.667)		(3.763)		(3.930)	
		Median	26.80		25.30		25.60		26.50	
		Min, Max	19.1, 34.9		18.6, 32.9		19.4, 34.3		18.6, 34.9	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change value	Raw value	Change value	Raw value	Change value	Raw value	Change
Body Mass Index (kg/m ²)	Day 6/Discharge Confinement	n	79	79	40	40	35	35	154	154
		Mean	26.81	-0.24	25.44	-0.20	25.93	-0.30	26.25	-0.24
		(SD)	(4.080)	(0.426)	(3.507)	(0.311)	(3.781)	(0.543)	(3.893)	(0.429)
		Median	26.80	-0.20	25.10	-0.20	25.40	-0.20	26.20	-0.20
		Min, Max	19.1, 34.7	-1.7, 1.0	18.5, 32.9	-0.9, 0.4	18.8, 34.2	-2.1, 0.4	18.5, 34.7	-2.1, 1.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change value	Raw value	Change value	Raw value	Change value	Raw value	Change
Body Mass Index (kg/m ²)	Day 30	n	77	77	39	39	33	33	149	149
		Mean	27.31	0.28	25.92	0.21	26.51	0.26	26.77	0.26
		(SD)	(4.214)	(0.543)	(3.699)	(0.442)	(3.602)	(0.735)	(3.975)	(0.565)
		Median	27.20	0.30	25.70	0.20	25.70	0.20	26.80	0.30
		Min, Max	19.4, 35.0	-1.1, 1.5	19.3, 32.9	-0.7, 1.0	20.0, 34.5	-1.5, 2.3	19.3, 35.0	-1.5, 2.3

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

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**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change value	Raw value	Change value	Raw value	Change value	Raw value	Change
Body Mass Index (kg/m ²)	Day 60	n	74	74	37	37	31	31	142	142
		Mean	27.19	0.29	26.01	0.34	26.41	0.32	26.71	0.31
		(SD)	(4.236)	(0.776)	(3.733)	(0.565)	(3.494)	(0.767)	(3.964)	(0.721)
		Median	26.95	0.20	26.20	0.30	26.10	0.30	26.70	0.30
		Min, Max	19.5, 35.8	-2.2, 1.9	19.5, 33.0	-0.7, 1.5	19.7, 35.0	-0.9, 2.0	19.5, 35.8	-2.2, 2.0

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change value	Raw value	Change value	Raw value	Change value	Raw value	Change
Body Mass Index (kg/m ²)	Day 91/Discharge n Ambulatory		74	74	35	35	33	33	142	142
		Mean	27.11	0.14	26.17	0.26	26.51	0.26	26.74	0.20
		(SD)	(4.271)	(1.012)	(3.805)	(0.733)	(3.703)	(0.949)	(4.026)	(0.932)
		Median	27.25	0.30	26.30	0.20	26.00	0.30	26.60	0.30
		Min, Max	19.3, 35.9	-2.8, 2.4	19.2, 33.0	-1.1, 2.7	19.8, 34.4	-1.7, 2.3	19.2, 35.9	-2.8, 2.7

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

Appendix 15.3.6.9

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**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Body Mass Index Categorical	Baseline	Underweight	0	0	0	0
		Normal weight	26 (32.5%)	18 (43.9%)	19 (48.7%)	63 (39.4%)
		Overweight	32 (40.0%)	16 (39.0%)	13 (33.3%)	61 (38.1%)
		Obese	21 (26.3%)	7 (17.1%)	7 (17.9%)	35 (21.9%)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

Appendix 15.3.6.9

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**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Body Mass Index Categorical	Day 6/Discharge Confinement	Underweight	0	0	0	0
		Normal weight	27 (33.8%)	19 (46.3%)	17 (43.6%)	63 (39.4%)
		Overweight	33 (41.3%)	16 (39.0%)	13 (33.3%)	62 (38.8%)
		Obese	19 (23.8%)	5 (12.2%)	5 (12.8%)	29 (18.1%)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

Appendix 15.3.6.9

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**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Body Mass Index Categorical	Day 30	Underweight	0	0	0	0
		Normal weight	23 (28.8%)	18 (43.9%)	12 (30.8%)	53 (33.1%)
		Overweight	33 (41.3%)	13 (31.7%)	16 (41.0%)	62 (38.8%)
		Obese	21 (26.3%)	8 (19.5%)	5 (12.8%)	34 (21.3%)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

Appendix 15.3.6.9

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**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Body Mass Index Categorical	Day 60	Underweight	0	0	0	0
		Normal weight	23 (28.8%)	16 (39.0%)	11 (28.2%)	50 (31.3%)
		Overweight	33 (41.3%)	13 (31.7%)	16 (41.0%)	62 (38.8%)
		Obese	18 (22.5%)	8 (19.5%)	4 (10.3%)	30 (18.8%)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

Appendix 15.3.6.9

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**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)	mCC (N=41)	SA (N=39)	Overall Safety (N=160)
			Raw value	Raw value	Raw value	Raw value
Body Mass Index Categorical	Day 91/Discharge Ambulatory	Underweight	0	0	0	0
		Normal weight	24 (30.0%)	14 (34.1%)	12 (30.8%)	50 (31.3%)
		Overweight	30 (37.5%)	13 (31.7%)	16 (41.0%)	59 (36.9%)
		Obese	20 (25.0%)	8 (19.5%)	5 (12.8%)	33 (20.6%)

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

Appendix 15.3.6.9

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**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Height (cm)	Baseline	n	79		41		39		159	
		Mean	170.72		171.24		170.73		170.85	
		(SD)	(8.683)		(9.548)		(8.900)		(8.911)	
		Median	172.00		171.60		171.30		171.60	
		Min, Max	149.0, 184.0		151.0, 188.5		152.9, 189.0		149.0, 189.0	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change value	Raw value	Change value	Raw value	Change value	Raw value	Change
Waist Circumference (cm)	Baseline	n	79		41		39		159	
		Mean	95.7		93.8		92.1		94.3	
		(SD)	(18.33)		(20.74)		(11.57)		(17.58)	
		Median	94.0		91.0		91.0		92.0	
		Min, Max	28, 167		33, 169		73, 121		28, 169	

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

Appendix 15.3.6.9

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**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change	Raw value	Change	Raw value	Change	Raw value	Change
Waist Circumference (cm)	Day 30	n	1	1	0	0	0	0	1	1
		Mean	180.0	88.0					180.0	88.0
		(SD)	(NA)	(NA)					(NA)	(NA)
		Median	180.0	88.0					180.0	88.0
		Min, Max	180, 180	88, 88					180, 180	88, 88

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.24 Summary of Weight, Waist Circumference and BMI Results - Safety Population****Safety Time Period: Randomized Period**

Parameter (units)	Study Day	Statistic	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
			Raw value	Change value	Raw value	Change value	Raw value	Change value	Raw value	Change
Waist Circumference (cm)	Day 91/Discharge n Ambulatory		79	74	41	35	39	32	159	141
		Mean	98.7	3.3	95.2	1.7	94.4	2.7	96.7	2.7
		(SD)	(22.24)	(22.67)	(23.13)	(27.88)	(17.60)	(18.00)	(21.40)	(23.00)
		Median	95.0	1.0	92.0	1.0	91.0	0.5	92.0	1.0
		Min, Max	68, 181	-61, 91	33, 181	-70, 91	73, 173	-16, 97	33, 181	-70, 97

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Change is change from baseline, where baseline is defined as the last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.

**Table 15.2.6.25 Summary of Cough Assessments Over Study - Safety Population****Safety Time Period: Pre-Randomization Period**

Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test Only (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Has subject experienced cough in the study period assessed?										
Yes	18 (22.5%)	18	7 (17.1%)	7	9 (23.1%)	9	2 (40.0%)	2	36 (21.8%)	36
No	62 (77.5%)	62	33 (80.5%)	33	30 (76.9%)	30	1 (20.0%)	1	126 (76.4%)	126
Missing	0	0	1 (2.4%)	0	0	0	2 (40.0%)	0	3 (1.8%)	0
Intensity of cough										
n	18		7		9		2		36	
Very mild	8 (44.4%)	8	2 (28.6%)	2	5 (55.6%)	5	1 (50.0%)	1	16 (44.4%)	16
Mild	5 (27.8%)	5	4 (57.1%)	4	3 (33.3%)	3	0	0	12 (33.3%)	12
Moderate	4 (22.2%)	4	1 (14.3%)	1	1 (11.1%)	1	1 (50.0%)	1	7 (19.4%)	7
Severe	1 (5.6%)	1	0	0	0	0	0	0	1 (2.8%)	1
Very severe	0	0	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

**Table 15.2.6.25 Summary of Cough Assessments Over Study - Safety Population****Safety Time Period: Pre-Randomization Period**

Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test Only (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Frequency of cough										
n	18		7		9		2		36	
Rarely	5 (27.8%)	5	2 (28.6%)	2	0	0	0	0	7 (19.4%)	7
Sometimes	7 (38.9%)	7	4 (57.1%)	4	8 (88.9%)	8	2 (100%)	2	21 (58.3%)	21
Fairly often	5 (27.8%)	5	1 (14.3%)	1	1 (11.1%)	1	0	0	7 (19.4%)	7
Often	1 (5.6%)	1	0	0	0	0	0	0	1 (2.8%)	1
Almost always	0	0	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

**Table 15.2.6.25 Summary of Cough Assessments Over Study - Safety Population****Safety Time Period: Pre-Randomization Period**

Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test Only (N=5)		Overall Safety (N=165)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Amount of sputum produced										
n	18		7		9		2		36	
No sputum	10 (55.6%)	10	6 (85.7%)	6	1 (11.1%)	1	2 (100%)	2	19 (52.8%)	19
A moderate amount of sputum	7 (38.9%)	7	1 (14.3%)	1	8 (88.9%)	8	0	0	16 (44.4%)	16
A large amount of sputum	1 (5.6%)	1	0	0	0	0	0	0	1 (2.8%)	1
A very large amount of sputum	0	0	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

**Table 15.2.6.25 Summary of Cough Assessments Over Study - Safety Population****Safety Time Period: Randomization Period**

Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Has subject experienced cough in the study period assessed?								
Yes	38 (47.5%)	118	18 (43.9%)	65	18 (46.2%)	60	74 (46.3%)	243
No	42 (52.5%)	363	23 (56.1%)	193	21 (53.8%)	152	86 (53.8%)	708
Intensity of cough								
n	38		18		18		74	
Very mild	13 (34.2%)	21	6 (33.3%)	16	5 (27.8%)	16	24 (32.4%)	53
Mild	13 (34.2%)	21	8 (44.4%)	21	9 (50.0%)	16	30 (40.5%)	58
Moderate	11 (28.9%)	28	3 (16.7%)	6	3 (16.7%)	8	17 (23.0%)	42
Severe	0	0	1 (5.6%)	1	0	0	1 (1.4%)	1
Very severe	1 (2.6%)	1	0	0	1 (5.6%)	1	2 (2.7%)	2

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

**Table 15.2.6.25 Summary of Cough Assessments Over Study - Safety Population****Safety Time Period: Randomization Period**

Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Frequency of cough								
n	38		18		18		74	
Rarely	14 (36.8%)	19	5 (27.8%)	7	5 (27.8%)	10	24 (32.4%)	36
Sometimes	14 (36.8%)	28	7 (38.9%)	24	8 (44.4%)	18	29 (39.2%)	70
Fairly often	4 (10.5%)	6	3 (16.7%)	4	4 (22.2%)	6	11 (14.9%)	16
Often	3 (7.9%)	4	3 (16.7%)	5	1 (5.6%)	1	7 (9.5%)	10
Almost always	3 (7.9%)	3	0	0	0	0	3 (4.1%)	3

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

**Table 15.2.6.25 Summary of Cough Assessments Over Study - Safety Population****Safety Time Period: Randomization Period**

Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Amount of sputum produced								
n	38		18		18		74	
No sputum	19 (50.0%)	32	9 (50.0%)	29	7 (38.9%)	15	35 (47.3%)	76
A moderate amount of sputum	17 (44.7%)	53	7 (38.9%)	18	11 (61.1%)	39	35 (47.3%)	110
A large amount of sputum	1 (2.6%)	1	2 (11.1%)	2	0	0	3 (4.1%)	3
A very large amount of sputum	1 (2.6%)	4	0	0	0	0	1 (1.4%)	4

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Pre-Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
		n(%)	Event s	n(%)	Event s	n(%)	Event s	n(%)	Event s	n(%)	Event s
Day 0	Has subject experienced cough in the study period assessed?										
	Yes	18 (22.5%)	18	7 (17.1%)	7	9 (23.1%)	9	2 (40.0%)	2	36 (21.8%)	36
	No	62 (77.5%)	62	33 (80.5%)	33	30 (76.9%)	30	1 (20.0%)	1	126 (76.4%)	126
	Missing			1 (2.4%)	0			2 (40.0%)	0	3 (1.8%)	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

Appendix 15.3.6.23

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Pre-Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
		n(%)	Event s	n(%)	Event s	n(%)	Event s	n(%)	Event s	n(%)	Event s
Day 0	VAS										
	n	18		7		9		2		36	
	Mean (SD)	27.8 (28.06)		18.1 (18.09)		20.8 (13.17)		44.5 (3.54)		25.1 (22.77)	
	Median	20.5		9.0		24.0		44.5		22.5	
	Min, Max	1, 100		0, 46		1, 40		42, 47		0, 100	

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

Appendix 15.3.6.23

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Pre-Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 0	Intensity of cough										
	n	18		7		9		2		36	
	Very mild	8 (44.4%)	8	2 (28.6%)	2	5 (55.6%)	5	1 (50.0%)	1	16 (44.4%)	16
	Mild	5 (27.8%)	5	4 (57.1%)	4	3 (33.3%)	3	0	0	12 (33.3%)	12
	Moderate	4 (22.2%)	4	1 (14.3%)	1	1 (11.1%)	1	1 (50.0%)	1	7 (19.4%)	7
	Severe	1 (5.6%)	1	0	0	0	0	0	0	1 (2.8%)	1
	Very severe	0	0	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

Appendix 15.3.6.23

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Pre-Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
		n(%)	Event s	n(%)	Event s	n(%)	Event s	n(%)	Event s	n(%)	Event s
Day 0	Frequency of cough										
	n	18		7		9		2		36	
	Rarely	5 (27.8%)	5	2 (28.6%)	2	0	0	0	0	7 (19.4%)	7
	Sometimes	7 (38.9%)	7	4 (57.1%)	4	8 (88.9%)	8	2 (100%)	2	21 (58.3%)	21
	Fairly often	5 (27.8%)	5	1 (14.3%)	1	1 (11.1%)	1	0	0	7 (19.4%)	7
	Often	1 (5.6%)	1	0	0	0	0	0	0	1 (2.8%)	1
	Almost always	0	0	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

Appendix 15.3.6.23

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Pre-Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Product Test (N=5)		Overall Safety (N=165)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 0	Amount of sputum produced										
	n	18		7		9		2		36	
	No sputum	10 (55.6%)	10	6 (85.7%)	6	1 (11.1%)	1	2 (100%)	2	19 (52.8%)	19
	A moderate amount of sputum	7 (38.9%)	7	1 (14.3%)	1	8 (88.9%)	8	0	0	16 (44.4%)	16
	A large amount of sputum	1 (5.6%)	1	0	0	0	0	0	0	1 (2.8%)	1
	A very large amount of sputum	0	0	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 1	Has subject experienced cough in the study period assessed?								
	Yes	15 (18.8%)	15	9 (22.0%)	9	11 (28.2%)	11	35 (21.9%)	35
	No	65 (81.3%)	65	32 (78.0%)	32	28 (71.8%)	28	125 (78.1%)	125

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 1	VAS								
	n	15		9		11		35	
	Mean (SD)	32.3 (31.44)		29.1 (27.71)		13.9 (13.11)		25.7 (26.56)	
	Median	23.0		20.0		10.0		15.0	
	Min, Max	0, 96		2, 90		0, 40		0, 96	

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

Appendix 15.3.6.23

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 1	Intensity of cough								
	n	15		9		11		35	
	Very mild	7 (46.7%)	7	4 (44.4%)	4	7 (63.6%)	7	18 (51.4%)	18
	Mild	5 (33.3%)	5	3 (33.3%)	3	4 (36.4%)	4	12 (34.3%)	12
	Moderate	3 (20.0%)	3	1 (11.1%)	1	0	0	4 (11.4%)	4
	Severe	0	0	1 (11.1%)	1	0	0	1 (2.9%)	1
	Very severe	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

Appendix 15.3.6.23

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 1	Frequency of cough								
	n	15		9		11		35	
	Rarely	4 (26.7%)	4	3 (33.3%)	3	5 (45.5%)	5	12 (34.3%)	12
	Sometimes	6 (40.0%)	6	4 (44.4%)	4	4 (36.4%)	4	14 (40.0%)	14
	Fairly often	3 (20.0%)	3	1 (11.1%)	1	2 (18.2%)	2	6 (17.1%)	6
	Often	2 (13.3%)	2	1 (11.1%)	1	0	0	3 (8.6%)	3
	Almost always	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 1	Amount of sputum produced								
	n	15		9		11		35	
	No sputum	5 (33.3%)	5	7 (77.8%)	7	3 (27.3%)	3	15 (42.9%)	15
	A moderate amount of sputum	10 (66.7%)	10	2 (22.2%)	2	8 (72.7%)	8	20 (57.1%)	20
	A large amount of sputum	0	0	0	0	0	0	0	0
	A very large amount of sputum	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 2	Has subject experienced cough in the study period assessed?								
	Yes	17 (21.3%)	17	11 (26.8%)	11	12 (30.8%)	12	40 (25.0%)	40
	No	63 (78.8%)	63	29 (70.7%)	29	22 (56.4%)	22	114 (71.3%)	114
	Missing			1 (2.4%)	0	5 (12.8%)	0	6 (3.8%)	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 2	VAS								
	n	17		11		12		40	
	Mean (SD)	21.9 (20.30)		20.8 (26.47)		17.0 (14.72)		20.1 (20.35)	
	Median	15.0		13.0		12.0		13.5	
	Min, Max	0, 71		2, 96		1, 48		0, 96	

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 2	Intensity of cough								
	n	17		11		12		40	
	Very mild	10 (58.8%)	10	7 (63.6%)	7	7 (58.3%)	7	24 (60.0%)	24
	Mild	4 (23.5%)	4	3 (27.3%)	3	4 (33.3%)	4	11 (27.5%)	11
	Moderate	3 (17.6%)	3	1 (9.1%)	1	1 (8.3%)	1	5 (12.5%)	5
	Severe	0	0	0	0	0	0	0	0
	Very severe	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 2	Frequency of cough								
	n	17		11		12		40	
	Rarely	7 (41.2%)	7	5 (45.5%)	5	4 (33.3%)	4	16 (40.0%)	16
	Sometimes	6 (35.3%)	6	5 (45.5%)	5	6 (50.0%)	6	17 (42.5%)	17
	Fairly often	3 (17.6%)	3	0	0	2 (16.7%)	2	5 (12.5%)	5
	Often	1 (5.9%)	1	1 (9.1%)	1	0	0	2 (5.0%)	2
	Almost always	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 2	Amount of sputum produced								
	n	17		11		12		40	
	No sputum	10 (58.8%)	10	10 (90.9%)	10	4 (33.3%)	4	24 (60.0%)	24
	A moderate amount of sputum	6 (35.3%)	6	1 (9.1%)	1	8 (66.7%)	8	15 (37.5%)	15
	A large amount of sputum	0	0	0	0	0	0	0	0
	A very large amount of sputum	1 (5.9%)	1	0	0	0	0	1 (2.5%)	1

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 3	Has subject experienced cough in the study period assessed?								
	Yes	17 (21.3%)	17	7 (17.1%)	7	8 (20.5%)	8	32 (20.0%)	32
	No	63 (78.8%)	63	33 (80.5%)	33	26 (66.7%)	26	122 (76.3%)	122
	Missing			1 (2.4%)	0	5 (12.8%)	0	6 (3.8%)	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 3	VAS								
	n	17		7		8		32	
	Mean (SD)	30.6 (27.35)		30.0 (30.87)		12.9 (17.38)		26.1 (26.43)	
	Median	15.0		20.0		6.5		14.5	
	Min, Max	0, 99		6, 95		0, 52		0, 99	

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 3	Intensity of cough								
	n	17		7		8		32	
	Very mild	9 (52.9%)	9	4 (57.1%)	4	5 (62.5%)	5	18 (56.3%)	18
	Mild	5 (29.4%)	5	2 (28.6%)	2	2 (25.0%)	2	9 (28.1%)	9
	Moderate	3 (17.6%)	3	1 (14.3%)	1	1 (12.5%)	1	5 (15.6%)	5
	Severe	0	0	0	0	0	0	0	0
	Very severe	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 3	Frequency of cough								
	n	17		7		8		32	
	Rarely	5 (29.4%)	5	2 (28.6%)	2	4 (50.0%)	4	11 (34.4%)	11
	Sometimes	5 (29.4%)	5	4 (57.1%)	4	2 (25.0%)	2	11 (34.4%)	11
	Fairly often	5 (29.4%)	5	1 (14.3%)	1	1 (12.5%)	1	7 (21.9%)	7
	Often	0	0	0	0	1 (12.5%)	1	1 (3.1%)	1
	Almost always	2 (11.8%)	2	0	0	0	0	2 (6.3%)	2

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 3	Amount of sputum produced								
	n	17		7		8		32	
	No sputum	9 (52.9%)	9	4 (57.1%)	4	4 (50.0%)	4	17 (53.1%)	17
	A moderate amount of sputum	7 (41.2%)	7	3 (42.9%)	3	4 (50.0%)	4	14 (43.8%)	14
	A large amount of sputum	1 (5.9%)	1	0	0	0	0	1 (3.1%)	1
	A very large amount of sputum	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 4	Has subject experienced cough in the study period assessed?								
	Yes	17 (21.3%)	17	8 (19.5%)	8	12 (30.8%)	12	37 (23.1%)	37
	No	63 (78.8%)	63	32 (78.0%)	32	22 (56.4%)	22	117 (73.1%)	117
	Missing			1 (2.4%)	0	5 (12.8%)	0	6 (3.8%)	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 4	VAS								
	n	17		8		12		37	
	Mean (SD)	27.3 (25.02)		29.9 (30.82)		19.9 (20.34)		25.5 (24.61)	
	Median	17.0		23.0		15.0		17.0	
	Min, Max	0, 90		5, 97		0, 62		0, 97	

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 4	Intensity of cough								
	n	17		8		12		37	
	Very mild	6 (35.3%)	6	3 (37.5%)	3	6 (50.0%)	6	15 (40.5%)	15
	Mild	6 (35.3%)	6	3 (37.5%)	3	4 (33.3%)	4	13 (35.1%)	13
	Moderate	5 (29.4%)	5	2 (25.0%)	2	2 (16.7%)	2	9 (24.3%)	9
	Severe	0	0	0	0	0	0	0	0
	Very severe	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 4	Frequency of cough								
	n	17		8		12		37	
	Rarely	8 (47.1%)	8	3 (37.5%)	3	4 (33.3%)	4	15 (40.5%)	15
	Sometimes	6 (35.3%)	6	4 (50.0%)	4	8 (66.7%)	8	18 (48.6%)	18
	Fairly often	1 (5.9%)	1	1 (12.5%)	1	0	0	2 (5.4%)	2
	Often	2 (11.8%)	2	0	0	0	0	2 (5.4%)	2
	Almost always	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 4	Amount of sputum produced								
	n	17		8		12		37	
	No sputum	8 (47.1%)	8	4 (50.0%)	4	6 (50.0%)	6	18 (48.6%)	18
	A moderate amount of sputum	8 (47.1%)	8	4 (50.0%)	4	6 (50.0%)	6	18 (48.6%)	18
	A large amount of sputum	1 (5.9%)	1	0	0	0	0	1 (2.7%)	1
	A very large amount of sputum	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 5	Has subject experienced cough in the study period assessed?								
	Yes	18 (22.5%)	18	9 (22.0%)	9	9 (23.1%)	9	36 (22.5%)	36
	No	62 (77.5%)	62	31 (75.6%)	31	25 (64.1%)	25	118 (73.8%)	118
	Missing			1 (2.4%)	0	5 (12.8%)	0	6 (3.8%)	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 5	VAS								
	n	18		9		9		36	
	Mean (SD)	23.6 (24.56)		16.6 (12.85)		24.9 (27.23)		22.1 (22.61)	
	Median	16.5		16.0		15.0		16.0	
	Min, Max	0, 96		0, 37		1, 78		0, 96	

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 5	Intensity of cough								
	n	18		9		9		36	
	Very mild	10 (55.6%)	10	3 (33.3%)	3	2 (22.2%)	2	15 (41.7%)	15
	Mild	5 (27.8%)	5	5 (55.6%)	5	4 (44.4%)	4	14 (38.9%)	14
	Moderate	3 (16.7%)	3	1 (11.1%)	1	3 (33.3%)	3	7 (19.4%)	7
	Severe	0	0	0	0	0	0	0	0
	Very severe	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 5	Frequency of cough								
	n	18		9		9		36	
	Rarely	9 (50.0%)	9	4 (44.4%)	4	2 (22.2%)	2	15 (41.7%)	15
	Sometimes	5 (27.8%)	5	4 (44.4%)	4	5 (55.6%)	5	14 (38.9%)	14
	Fairly often	2 (11.1%)	2	1 (11.1%)	1	2 (22.2%)	2	5 (13.9%)	5
	Often	1 (5.6%)	1	0	0	0	0	1 (2.8%)	1
	Almost always	1 (5.6%)	1	0	0	0	0	1 (2.8%)	1

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 5	Amount of sputum produced								
	n	18		9		9		36	
	No sputum	9 (50.0%)	9	7 (77.8%)	7	3 (33.3%)	3	19 (52.8%)	19
	A moderate amount of sputum	8 (44.4%)	8	2 (22.2%)	2	6 (66.7%)	6	16 (44.4%)	16
	A large amount of sputum	1 (5.6%)	1	0	0	0	0	1 (2.8%)	1
	A very large amount of sputum	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 6/Discharge Confinement	Has subject experienced cough in the study period assessed?								
	Yes	17 (21.3%)	17	8 (19.5%)	8	7 (17.9%)	7	32 (20.0%)	32
	No	63 (78.8%)	63	32 (78.0%)	32	27 (69.2%)	27	122 (76.3%)	122
	Missing			1 (2.4%)	0	5 (12.8%)	0	6 (3.8%)	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 6/Discharge Confinement	VAS								
	n	17		8		7		32	
	Mean (SD)	19.2 (26.76)		16.4 (10.55)		29.4 (29.29)		20.7 (24.17)	
	Median	10.0		17.5		21.0		12.0	
	Min, Max	0, 96		1, 33		2, 78		0, 96	

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 6/Discharge Confinement	Intensity of cough								
	n	17		8		7		32	
	Very mild	8 (47.1%)	8	4 (50.0%)	4	3 (42.9%)	3	15 (46.9%)	15
	Mild	4 (23.5%)	4	3 (37.5%)	3	1 (14.3%)	1	8 (25.0%)	8
	Moderate	4 (23.5%)	4	1 (12.5%)	1	2 (28.6%)	2	7 (21.9%)	7
	Severe	0	0	0	0	0	0	0	0
	Very severe	1 (5.9%)	1	0	0	1 (14.3%)	1	2 (6.3%)	2

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 6/Discharge Confinement	Frequency of cough								
	n	17		8		7		32	
	Rarely	8 (47.1%)	8	5 (62.5%)	5	2 (28.6%)	2	15 (46.9%)	15
	Sometimes	4 (23.5%)	4	3 (37.5%)	3	5 (71.4%)	5	12 (37.5%)	12
	Fairly often	4 (23.5%)	4	0	0	0	0	4 (12.5%)	4
	Often	1 (5.9%)	1	0	0	0	0	1 (3.1%)	1
	Almost always	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 6/Discharge Confinement	Amount of sputum produced								
	n	17		8		7		32	
	No sputum	6 (35.3%)	6	4 (50.0%)	4	1 (14.3%)	1	11 (34.4%)	11
	A moderate amount of sputum	10 (58.8%)	10	4 (50.0%)	4	6 (85.7%)	6	20 (62.5%)	20
	A large amount of sputum	0	0	0	0	0	0	0	0
	A very large amount of sputum	1 (5.9%)	1	0	0	0	0	1 (3.1%)	1

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 30	Has subject experienced cough in the study period assessed?								
	Yes	8 (10.0%)	8	4 (9.8%)	4	1 (2.6%)	1	13 (8.1%)	13
	No	68 (85.0%)	68	35 (85.4%)	35	32 (82.1%)	32	135 (84.4%)	135
	Missing	4 (5.0%)	0	2 (4.9%)	0	6 (15.4%)	0	12 (7.5%)	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 30	VAS								
	n	8		4		1		13	
	Mean (SD)	24.8 (28.35)		21.3 (15.48)		4.0 (NC)		22.1 (23.69)	
	Median	12.0		17.5		4.0		11.0	
	Min, Max	0, 78		8, 42		4, 4		0, 78	

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 30	Intensity of cough								
	n	8		4		1		13	
	Very mild	5 (62.5%)	5	2 (50.0%)	2	1 (100%)	1	8 (61.5%)	8
	Mild	0	0	1 (25.0%)	1	0	0	1 (7.7%)	1
	Moderate	3 (37.5%)	3	1 (25.0%)	1	0	0	4 (30.8%)	4
	Severe	0	0	0	0	0	0	0	0
	Very severe	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 30	Frequency of cough								
	n	8		4		1		13	
	Rarely	2 (25.0%)	2	1 (25.0%)	1	0	0	3 (23.1%)	3
	Sometimes	4 (50.0%)	4	2 (50.0%)	2	1 (100%)	1	7 (53.8%)	7
	Fairly often	0	0	1 (25.0%)	1	0	0	1 (7.7%)	1
	Often	2 (25.0%)	2	0	0	0	0	2 (15.4%)	2
	Almost always	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 30	Amount of sputum produced								
	n	8		4		1		13	
	No sputum	1 (12.5%)	1	2 (50.0%)	2	0	0	3 (23.1%)	3
	A moderate amount of sputum	6 (75.0%)	6	2 (50.0%)	2	1 (100%)	1	9 (69.2%)	9
	A large amount of sputum	1 (12.5%)	1	0	0	0	0	1 (7.7%)	1
	A very large amount of sputum	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 60	Has subject experienced cough in the study period assessed?								
	Yes	2 (2.5%)	2	4 (9.8%)	4	0	0	6 (3.8%)	6
	No	69 (86.3%)	69	31 (75.6%)	31	30 (76.9%)	30	130 (81.3%)	130
	Missing	9 (11.3%)	0	6 (14.6%)	0	9 (23.1%)	0	24 (15.0%)	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 60	VAS								
	n	2		4		0		6	
	Mean (SD)	29.0 (41.02)		45.8 (49.85)				40.2 (43.61)	
	Median	29.0		41.5				32.5	
	Min, Max	0, 58		0, 100				0, 100	

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 60	Intensity of cough								
	n	2		4		0		6	
	Very mild	0	0	1 (25.0%)	1	0	0	1 (16.7%)	1
	Mild	0	0	2 (50.0%)	2	0	0	2 (33.3%)	2
	Moderate	2 (100%)	2	1 (25.0%)	1	0	0	3 (50.0%)	3
	Severe	0	0	0	0	0	0	0	0
	Very severe	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 60	Frequency of cough								
	n	2		4		0		6	
	Rarely	0	0	1 (25.0%)	1	0	0	1 (16.7%)	1
	Sometimes	0	0	1 (25.0%)	1	0	0	1 (16.7%)	1
	Fairly often	2 (100%)	2	0	0	0	0	2 (33.3%)	2
	Often	0	0	2 (50.0%)	2	0	0	2 (33.3%)	2
	Almost always	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 60	Amount of sputum produced								
	n	2		4		0		6	
	No sputum	1 (50.0%)	1	1 (25.0%)	1	0	0	2 (33.3%)	2
	A moderate amount of sputum	0	0	1 (25.0%)	1	0	0	1 (16.7%)	1
	A large amount of sputum	0	0	2 (50.0%)	2	0	0	2 (33.3%)	2
	A very large amount of sputum	1 (50.0%)	1	0	0	0	0	1 (16.7%)	1

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 90	Has subject experienced cough in the study period assessed?								
	Yes	7 (8.8%)	7	5 (12.2%)	5	0	0	12 (7.5%)	12
	No	66 (82.5%)	66	30 (73.2%)	30	31 (79.5%)	31	127 (79.4%)	127
	Missing	7 (8.8%)	0	6 (14.6%)	0	8 (20.5%)	0	21 (13.1%)	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

Note: The assessments performed at Day 0 to Day 6, Day 31, 61, and 91 are used to evaluate cough at Day - 1 to Day 5, Day 30, 60, and 90, respectively.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 90	VAS								
	n	5		3		0		8	
	Mean (SD)	21.8 (25.93)		45.3 (47.73)				30.6 (34.40)	
	Median	17.0		24.0				20.5	
	Min, Max	0, 64		12, 100				0, 100	

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

Note: Cough experienced in the previous 24h by the subjects is assessed in the morning of Day 0 to Day 6. If subject has answered question more than once then the most severe intensity is presented.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 90	Intensity of cough								
	n	7		5		0		12	
	Very mild	0	0	2 (40.0%)	2	0	0	2 (16.7%)	2
	Mild	5 (71.4%)	5	1 (20.0%)	1	0	0	6 (50.0%)	6
	Moderate	2 (28.6%)	2	2 (40.0%)	2	0	0	4 (33.3%)	4
	Severe	0	0	0	0	0	0	0	0
	Very severe	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 90	Frequency of cough								
	n	7		5		0		12	
	Rarely	2 (28.6%)	2	2 (40.0%)	2	0	0	4 (33.3%)	4
	Sometimes	3 (42.9%)	3	2 (40.0%)	2	0	0	5 (41.7%)	5
	Fairly often	2 (28.6%)	2	0	0	0	0	2 (16.7%)	2
	Often	0	0	1 (20.0%)	1	0	0	1 (8.3%)	1
	Almost always	0	0	0	0	0	0	0	0

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

Note: Percentages for 'Has the subject experienced a cough' are based on the number of subjects indicated in the column header (N). Percentages for intensity of cough are based on the number of subjects who have experienced a cough.

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**Table 15.2.6.25.1 Summary of Cough Assessments by Study Day - Safety Population****Safety Time Period: Randomization Period**

Study Day	Variable	THSm2.2 (N=80)		mCC (N=41)		SA (N=39)		Overall Safety (N=160)	
		n(%)	Events	n(%)	Events	n(%)	Events	n(%)	Events
Day 90	Amount of sputum produced								
	n	7		5		0		12	
	No sputum	2 (28.6%)	2	3 (60.0%)	3	0	0	5 (41.7%)	5
	A moderate amount of sputum	3 (42.9%)	3	2 (40.0%)	2	0	0	5 (41.7%)	5
	A large amount of sputum	1 (14.3%)	1	0	0	0	0	1 (8.3%)	1
	A very large amount of sputum	1 (14.3%)	1	0	0	0	0	1 (8.3%)	1

Note: 'Product Test' refers to all subjects who tested the THS product but were not randomized. The Overall Safety refers to all subjects exposed to THSm2.2.

Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.

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